FY2023 Financial Results

May 9, 2024

Santen Pharmaceutical Co., Ltd.

Featuring

Takeshi Ito
President &
Chief Executive Officer

- Presentation
- Q&A

Rie Nakajima
Chief Operating Officer

- Presentation
- Q&A

Kazuo Koshiji
Chief Financial Officer

- Presentation
- Q&A

Peter Sallstig
Chief Medical Officer

- Q&A

Agenda

Summary

Structural reforms completed ahead of schedule. Strong progress in medium-long term growth strategy implementation

FY2023

Achieved highest revenue and core OP

- Revenue: JPY 302.0 billion (+8.2%, YoY)
- Core OP: JPY 62.8 billion (+41.9%, YoY), OP: JPY 38.5 billion
- Core EPS: JPY 132.13 (+54%, YoY), EPS: JPY 72.59

FY2024 forecast

Increase operating profit (IFRS) and EPS

- Revenue: JPY 297.0 billion (-1.6%, YoY)
- Core OP: JPY 55.0 billion (-12.4%, YoY), OP: JPY 44.5 billion (+15.5% YoY)
- Core EPS: JPY 117.05 (-11%, YoY), EPS: JPY 92.22 (+27%, YoY)

Strong progress for medium-long term growth

- Improve profitability: Completed structural reforms including streamlining in Americas. Improved JPY 15.0 billion scale in profitability
- R&D: Approved *Alesion*[1] eyelid cream (Japan) and *Catiolanze* (EMEA), and made progress including myopia and ptosis areas
- Growth strategy: Pursue Commercial Excellence
  On-going discussion for inorganic growth including business development

Shareholder returns

- FY2023: JPY 33/share in dividend, JPY 16.2 billion in share buyback
- FY2024: JPY 34/share in dividend forecast, up to JPY 38.0 billion in share buyback (from May 10, 2024 to November 6, 2024)

1 *Alesion* is a registered trademark of Boehringer Ingelheim KG

Next medium-term management plan to be formulated by end of FY2024

Basic policy until FY2025

- Profit maximization through structural reforms and sales maximization of each region
- Lay the organizational groundwork for FY2026

KPI	FY2020	FY2021	FY2022	FY2023	FY2024 FCST	MTP FY2025
Revenue	JPY **249.6**bil.	JPY **266.3**bil.	JPY **279.0**bil.	JPY **302.0**bil.	JPY **297.0**bil.	JPY **280.0**bil.
Core operating profit/margin	JPY **50.1**bil / **20**%	JPY **46.3**bil / **17**%	JPY **44.2**bil / **16**%	JPY **62.8**bil / **21**%	JPY **55.0**bil / **19**%	JPY **56.0**bil / **20**%
Revenue growth ratio per overseas employee	**-1**% (CAGR for FY19-22 FCST)[1]			**33**%(YoY)[2]	**19**% (FY22ACT-24FCST CAGR)[2]	Over **7**% growth[3,4]
Core ROE	**12.3**%	**10.9**%	**10.5**%	**16.2**%	**14**%[5]	**13**%
Growth rate of core EPS	**+5**%(YoY) JPY 94.09	**-6**%(YoY) JPY 88.16	**-3**%(YoY) JPY 85.86	**+54**%(YoY) JPY 132.13	**+17**% (FY22ACT-24FCST CAGR)/ JPY117.05	Over **10**%[4]
EPS (IFRS)	JPY 23.30	JPY 68.07	JPY -38.60	JPY 72.59	JPY 92.22	-

1 China, Asia, EMEA. Excluding FX impact, calculated based on FY2022 FX rate 2 China, Asia, EMEA. Excluding *Ikervis* one-time factor in FY2023
3 China, Asia, EMEA. Excluding FX impact, calculated based on MTP rate 4 CAGR for FY2022 forecast- FY2025 5 Including share buy-back

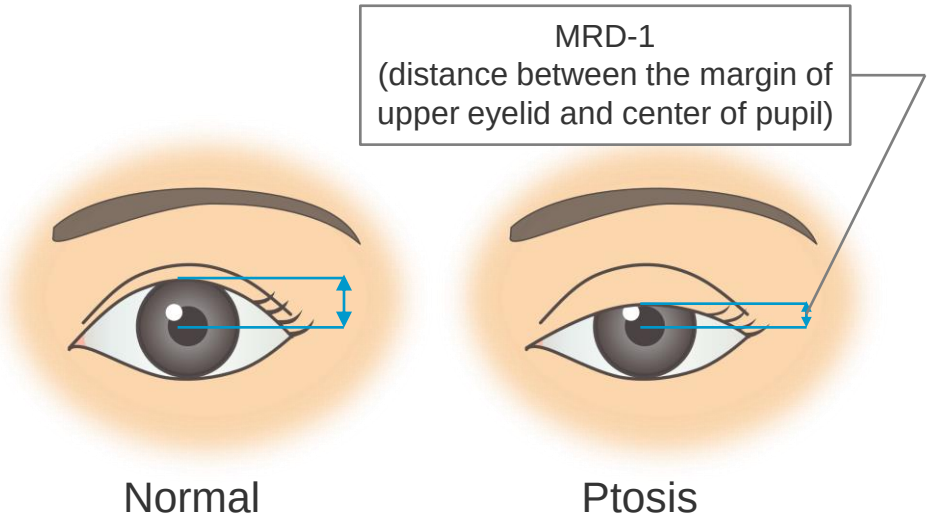
Achieved primary endpoint in P3 trial in Japan. Plan to file in FY2024

Ptosis

- Abnormal low-lying upper eyelid margin when opening the eye

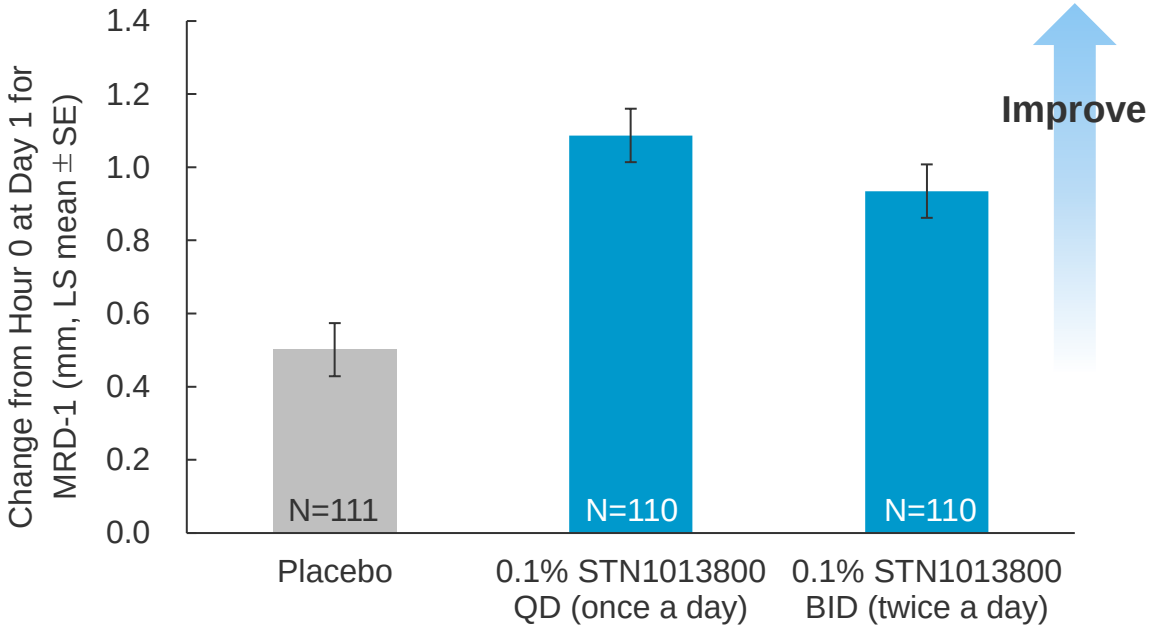
  Loss of upper vision
  shoulder stiffness, headache, fatigue, etc.

- Acquired ptosis is most commonly age-related
- Estimated potential acquired ptosis patients is approx. 30 million people in Japan[1]
- Current treatment is surgery



TLR in P3 trial in Japan

Primary endpoint: Change of MRD-1 at Day 15 Hours 2 after the first instillation



- Demonstrated statistical superiority of 0.1% STN10**138**00 QD/BID to placebo in change of MRD-1 at Day 15 Hours 2 after the first instillation
- Confirmed safety and tolerability of 0.1% STN10**138**00 QD/BID up to 6 months
- The efficacy and safety profile of 0.1% STN10**138**00 was consistent with US studies.

1. Santen estimate.

Maximize sales and contribution profit through executing regional strategies

Japan

Revenue: JPY 164.6 bil. / Contribution profit: JPY 59.1 bil.

Maintain business base for strategic products and new products penetration, amidst NHI price reduction, GE impacts and co-pay hikes for long-listed products

- Successful launch of new products
  - *Alesion* eyelid cream
  - *EYLEA* 8mg[2]
- Sales expansion for strategic products
  - *Eybelis, PRESERFLO MicroShunt*

Overseas[1]

Revenue: JPY 131.0 bil. / Contribution profit: JPY 52.0 bil.

Focus on pursuing Commercial Excellence to improve productivity and maximize product value for strategic products and new products

- EMEA: Focus on mainstay products in glaucoma and dry eye
  - Preservative-free glaucoma products, *Ikervis*, *PRESERFLO MicroShunt*
  - Launch new products focusing on market access (ROCK inhibitors, *Catiolanze*)
- Asia: Accelerate strategic products' growth
  - *Tapros, Tapcom, Eybelis, Ikervis*
  - Retail channel expansion
- China: Multi-channel strategy
  - Expand high-potential products (*Tapros, Cationorm, Sancoba*)

1 China, Asia and EMEA
2 Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

FY2024 expected major events on in-house pipeline

Strengthen glaucoma portfolio in EMEA and Asia
Aim to achieve key milestones for launch in myopia and ptosis

		Data readout	Filing	Approval	Launch
Existing area	Glaucoma	Netarsudil mesilate P3 long-term STN10**139**00 Japan *Confirmed superiority to repasudil	Sepetaprost STN10**126**00, Japan Latanoprost cationic emulsion STN10**130**01, Asia	Tafluprost / timolol maleate STN10**111**01, China	*Catiolanze* STN10**130**01, Europe *Rhopressa* STN10**139**00, Asia *Rocklatan* STN10**140**00, Asia *Eybelis Mini* (PFUD[1]) STN10**117**02, Asia
	Dry eye				*Diquas LX* STN10**089**03, Asia
	Allergy				*Alesion* eyelid cream STN10**114**02, Japan *Alesion LX* STN10**114**01, Asia
New area	Myopia	AFDX0250BS P2a STN10**134**00, Japan		Atropine sulfate STN10**127**00, Japan	
	Ptosis		Oxymetazoline HCl STN10**138**00, Japan		

The pipelines listed here are only those for which disclosure has been agreed upon with each partner company. Not all planned pipelines or development regions are specified. The schedule is based on the best-case scenario assumed as of March 31, 2024, and does not guarantee launch. 1 Preservative Free Unit Dose

Alesion eyelid cream 0.5%, a treatment for allergic conjunctivitis

Aim to support all day comfort for patients,
advancing the treatment concept of proactive instillation

4times/day

Alesion

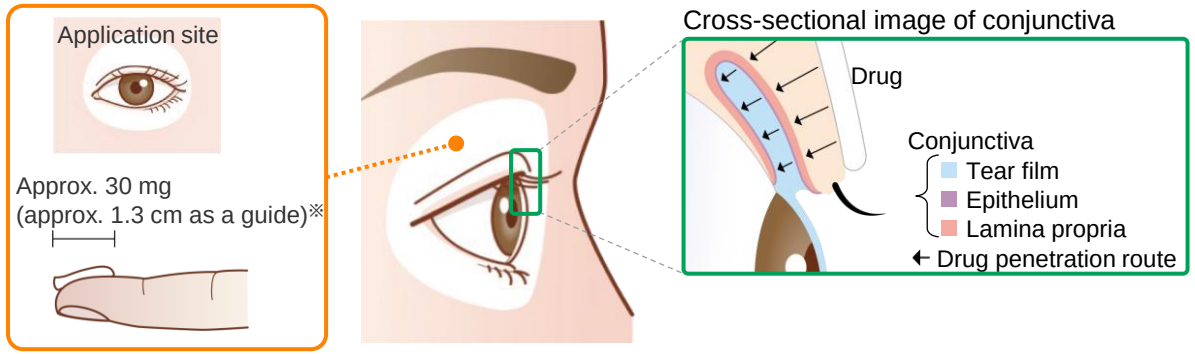
2times/day

Alesion LX

1time/day

Alesion
eyelid cream

■ Approx. 30 mg per eye (approx. 1.3 cm as a guide)



※Volume per an eyelid (upper and lower)
(About half length from tip to distal interphalangeal joint at the index finger in adult)

■ Cream formulation, less “stickiness” than ointment

“How was the ease of usage?”
Questionnaires for subjects in phase III long-term study (n=124)

“I use as instructed without any problem with the application comfort"
or
“Slight discomfort but I can prioritize usage based on instructions"

98.4%

FY2023 Consolidated results

Strong progress in revenue and core operating profit. Overseas business driving growth

	FY2022 ACT	FY2023 ACT
USD (JPY)	135.40	144.80
EUR (JPY)	140.97	156.88
CNY (JPY)	19.72	20.24

(JPY billions)	FY2022		FY2023				
	Actual	vs Revenue	Actual	vs Revenue	YoY	Forecast (Nov. 7)	vs forecast
Revenue	279.0	-	**302.0**	**-**	**+8.2%**	302.0	100%
Cost of sales	113.0	40%	123.1	41%	+9.0%	121.0	102%
Gross profit	166.1	60%	**178.9**	**59%**	**+7.7%**	181.0	99%
SG&A expenses	93.5	34%	90.8	30%	-2.9%	94.0	97%
R&D expenses	28.3	10%	25.3	8%	-10.7%	29.0	87%
Core operating profit	44.2	16%	**62.8**	**21%**	**+41.9%**	58.0	108%
Non-core expenses	2.7	1%	1.0	0%	-62.6%	1.1	92%
Amortization on intangible assets associated with products	9.5	3%	9.5	3%	-0.5%	9.4	101%
Other income	3.5	1%	1.5	1%	-56.1%	1.5	103%
Other expenses	38.6	14%	15.3	5%	-60.4%	8.0	191%
Operating profit	-3.1	-	**38.5**	**13%**	**-**	41.0	94%
Finance income	1.2	0%	1.6	1%	+36.4%	1.5	105%
Finance expenses	1.5	1%	2.7	1%	+77.7%	1.2	222%
Share of loss of investments accounted for using equity method	2.4	1%	7.6	3%	+220.7%	3.0	252%
Profit before tax	-5.8	-	29.9	10%	-	38.3	78%
Income tax expenses	9.2	3%	3.2	1%	-65.5%	8.8	36%
Actual tax ratio	-	-	*10.6%*	-	-	*23%*	-
Net profit	-15.0	-	**26.7**	**9%**	**-**	29.5	91%
Core net profit	33.2	12%	48.5	16%	+46.0%	43.5	112%

Revenue: +8.2%

- Overseas business+24% YoY*1

Gross profit: +7.7%

- COGS ratio increase versus forecast mainly resulting from region/product mix

Core OP: +41.9%

- Reduced SG&A from cost optimization and structural reforms

OP (IFRS)

- Structural reforms costs, Noto plant operating loss, impairment loss (intangible asset related to cell therapy products JPY 7.0 billion) and others

Net profit (IFRS)

- Share of loss of investments (including Twenty Twenty Therapeutics)
- Tax ratio excluding one-time factors : 23.8% (FY2023)

*1 China, Asia and EMEA (including one-time factors)

Decrease in revenue from GE impacts and other factors in Japan
Increase in profits and EPS in IFRS basis

	FY2023 ACT	FY2024 FCST
USD (JPY)	144.80	145.00
EUR (JPY)	156.88	155.00
CNY (JPY)	20.24	20.00

(JPY billions)	FY2023		FY2024		
	Actual	vs Revenue	Forecast	vs Revenue	YoY
Revenue	302.0	-	**297.0**	**-**	**-1.6%**
Cost of sales	123.1	41%	127.5	43%	+3.6%
Gross profit	178.9	59%	**169.5**	**57%**	**-5.2%**
SG&A expenses	90.8	30%	88.5	30%	-2.6%
R&D expenses	25.3	8%	26.0	9%	+2.9%
Core operating profit	62.8	21%	**55.0**	**19%**	**-12.4%**
Non-core expenses	1.0	0%	-	-	-100.0%
Amortization on intangible assets associated with products	9.5	3%	8.8	3%	-7.1%
Other income	1.5	1%	0.7	0%	-54.8%
Other expenses	15.3	5%	2.4	1%	-84.3%
Operating profit	38.5	13%	**44.5**	**15%**	**+15.5%**
Finance income	1.6	1%	2.0	1%	+27.2%
Finance expenses	2.7	1%	1.5	1%	-43.7%
Share of loss of investments accounted for using equity method	7.6	3%	-	-	-100.0%
Profit before tax	29.9	10%	45.0	15%	+50.6%
Income tax expenses	3.2	1%	11.5	4%	+262.6%
Actual tax ratio	*10.6%*	-	*26%*	-	-
Net profit	26.7	9%	**33.5**	**11%**	**+25.5%**
ROE	8.9%		11%		
Core ROE	16.2%		14%		
Core net profit	48.5	16%	41.3	14%	-15.0%

Revenue: -1.6%

- Impacted by GEs, NHI price reduction and co-pay hikes for long-listed products in Japan. Growth trajectory in overseas

Gross profit: -5.2%

- Increase COGS ratio due to product mix and cost increase

Core OP: -12.4%

- Maintain same SG&A ratio level as FY2023

OP (IFRS): +15.5%

- Decrease in other expenses resulting from completion of structural reforms, and others

Net profit (IFRS): +25.5%

- EPS：Increase JPY 73 to JPY 92

Balanced cash allocation to investments and shareholder returns as planned

Operating cash flow in FY2023: JPY 72.6 billion (historically highest). Maintain strong momentum
3-year operating cash flow excluding R&D expenses until FY2025 to be JPY 250.0 billion scale (+JPY 60.0 billion from MTP)

Outflow

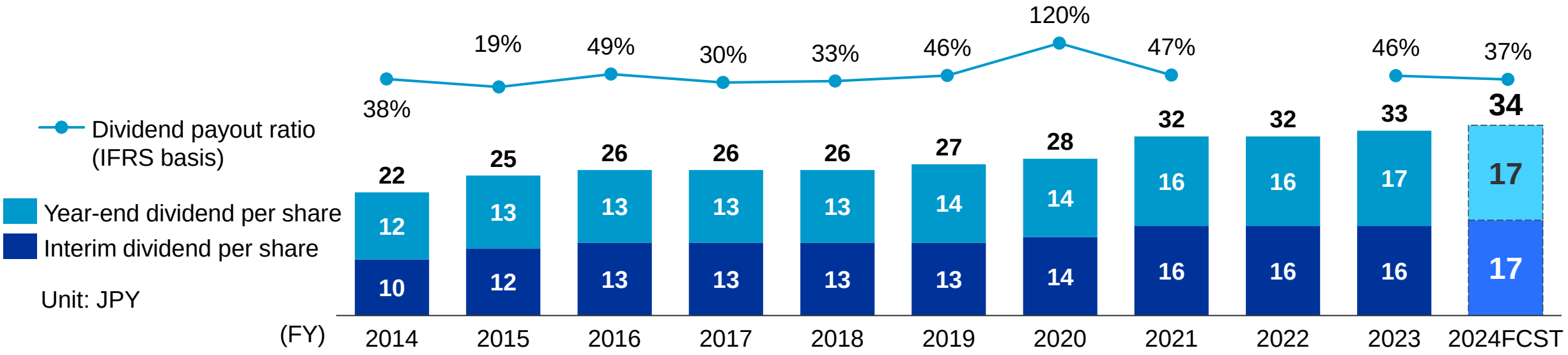
Use[1]		Amount[1]	FY2023 actual / outlook
Growth investments	Capital Expenditures	JPY 26.0 bil.	• FY2023: JPY 10.2 billion (production related) • Expect some investment in Noto plant, but totally decrease in big scale investment after FY2024
	Research and development expenses	Over JPY100.0 bil. Including development milestones	• FY2023: JPY25.3 billion • Prioritize investment including early-stage pipelines
	Business development investment	JPY 80.0 bil. to JPY 90.0 bil.	• Investment opportunities to contribute to cash flow and align with regional needs, capture global medium-long term growth
Shareholder returns	Share buybacks		• FY2023: JPY 16.2 billion, FY2024: JPY 38.0 billion (maximum) • Implement opportunistic share buybacks, factoring in business development opportunities and share price
	Dividend	JPY 37.5 bil.	• FY2023: JPY 11.9 billion (33 yen per share / annual basis) • Continue progressive dividend policy in line with medium-long term profit growth

1. Accumulation in FY2023-FY2025

Increased annual dividend forecast to JPY 34 on the back of completion of structural reforms and clarity on medium-long term sustainable profit levels

Medium-term management plan dividend policy:

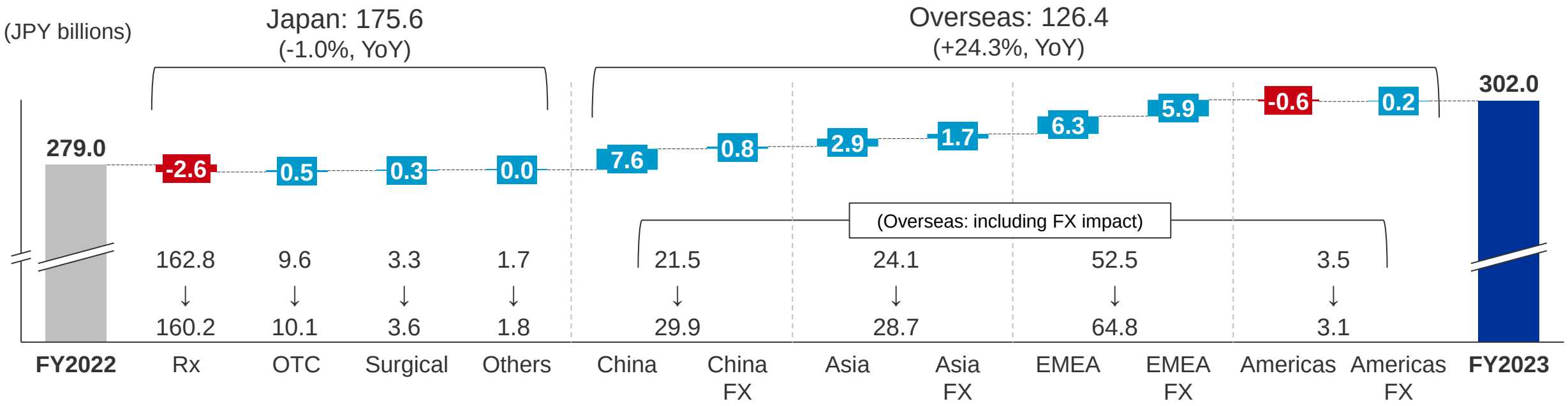
Continue progressive dividend policy in line with medium-long term profit growth, notwithstanding volatility from business environment



(FY)	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024FCST
Total return ratio (IFRS)	38%	19%	106%	30%	76%	46%	120%	47%	-	106%	154%
Share buy-back (JPY billions)	-	-	12.3	-	13.9	-	-	-	25.7	16.2	38.0 (max.)
Treasury shares cancellation (share)	-	-	8.30 mil.	-	7.50 mil.	-	-	-	24.87 mil.	12.00 mil.	-
EPS (JPY)	58.18	128.99	52.96	86.73	78.67	59.16	23.30	68.07	-38.60	72.59	92.22

Appendix

YoY sales growth of +5.2% (excluding FX impact) mainly driven by overseas

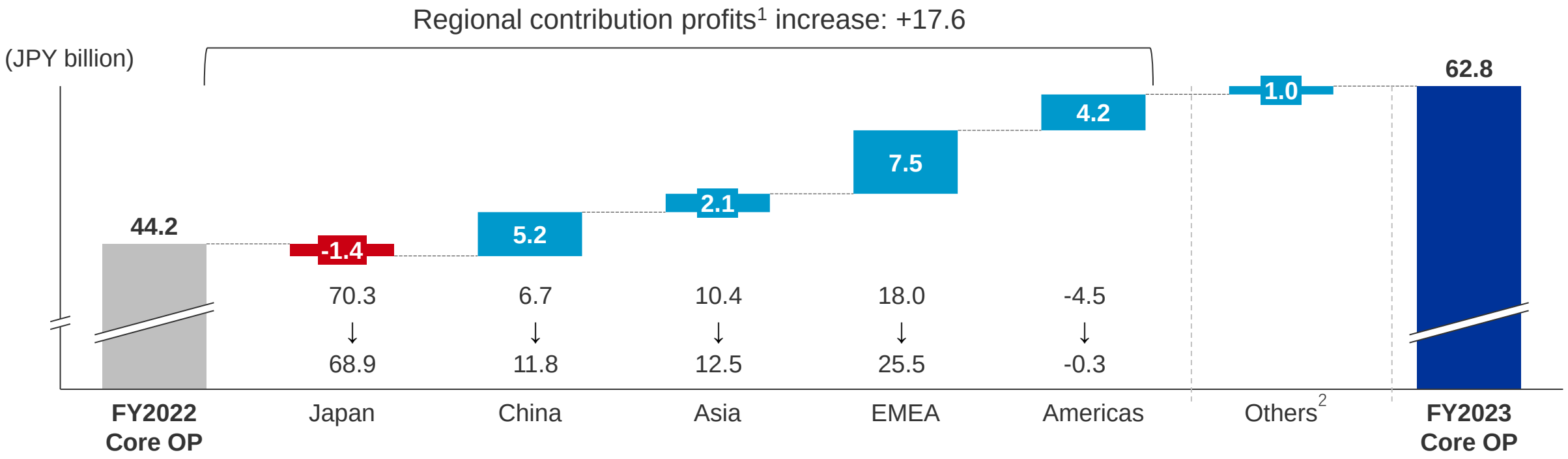


Japan	-1.0% YoY: Impacted *Tapros/Tapcom* GE coupled with decrease in *Alesion* resulting from decrease in pollen level versus last year
China	+38.6% YoY (Ex. FX impact +35.1%): Strong performance from multi-channel strategy coupled with market recovery from COVID-19
Asia	+18.9% YoY (Ex. FX impact +11.9%): Steady growth from mainstay products in key markets. Including impact of transient demand related to infection products in Vietnam
EMEA	+23.3% YoY (Ex. FX impact +12.1%): Continued growth in glaucoma products and *Ikervis* for dry eye in EU5 and Nordic. Including *Ikervis* one-time impact
Americas	-11.8% YoY (Ex. FX impact -16.5%): Completed streamlining of commercial business

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

FY2023 Core OP bridge

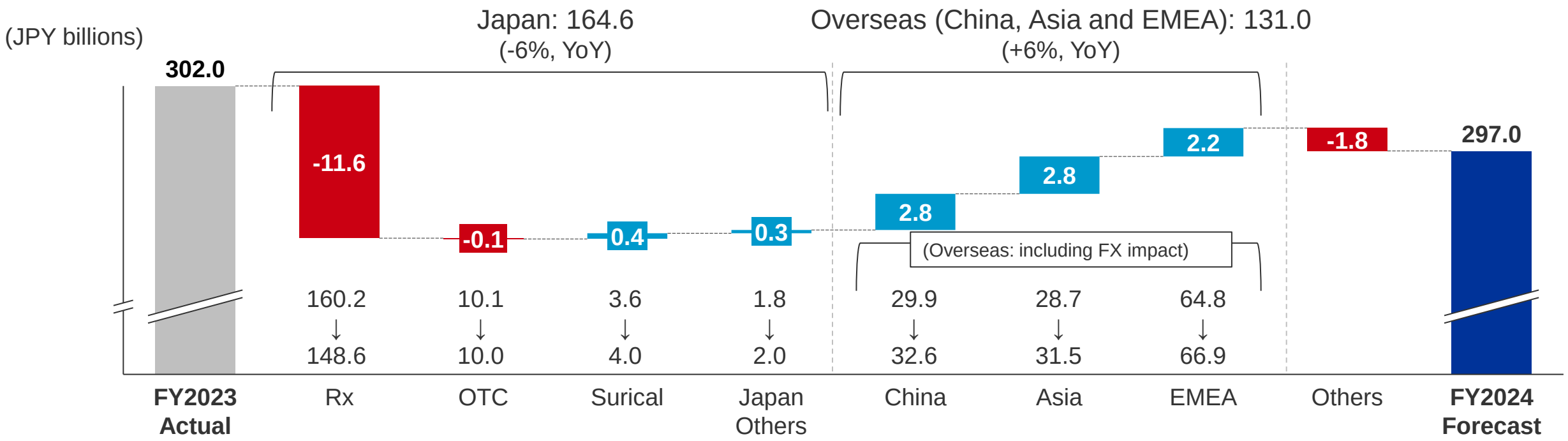
Significant improvement in Core OP from increase of contribution profit in overseas and structural reforms



Regional contribution profits	• Japan: Decreased contribution profit resulting from decreased revenue and increased COGS ratio impacted by product mix and others • Overseas: Increased contribution profit resulting from revenue increase in China including market recovery, Asia and EMEA, coupled with *Ikervis* one-time factor in EMEA
Others	• Decreased SG&A with effective of structural reforms, unused global R&D expenses and others

1 Including impact of reorganization in overseas reflets to contribution profits
2 R&D and back-office expenses in regions and global functions

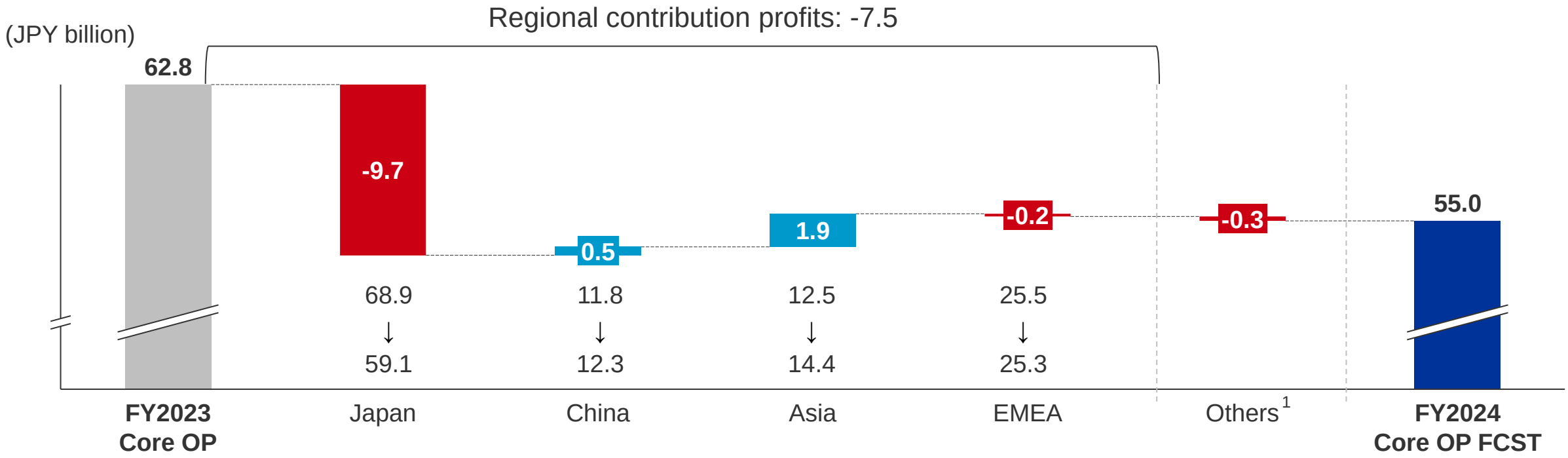
Stable growth from overseas



Japan	-6% YoY: Decrease resulting from GE impacts of mainstay products, NHI price reduction and other factors. Plan to increase in surgical business with *PRESERFLO MicroShunt*
China	+9% YoY (incl. FX impact): High-single digit growth impacted by *Diquas* VBP, despite of increase in *Hyalein, Tapros*, *Cationorm* and *Sancoba.*
Asia	+10% YoY (incl. FX impact): Mainly from core products in glaucoma and dry eye in South Korea and major countries. Including reactionary drop for infection products in Vietnam from FY2023 transient increase
EMEA	+3% YoY (incl. FX impact): Mainly from core products in glaucoma and dry eye in major countries. Including reactionary drop of *Ikervis* one-time factor from FY2023

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

Decrease in Core OP due to decrease of revenue and increase of COGS ratio

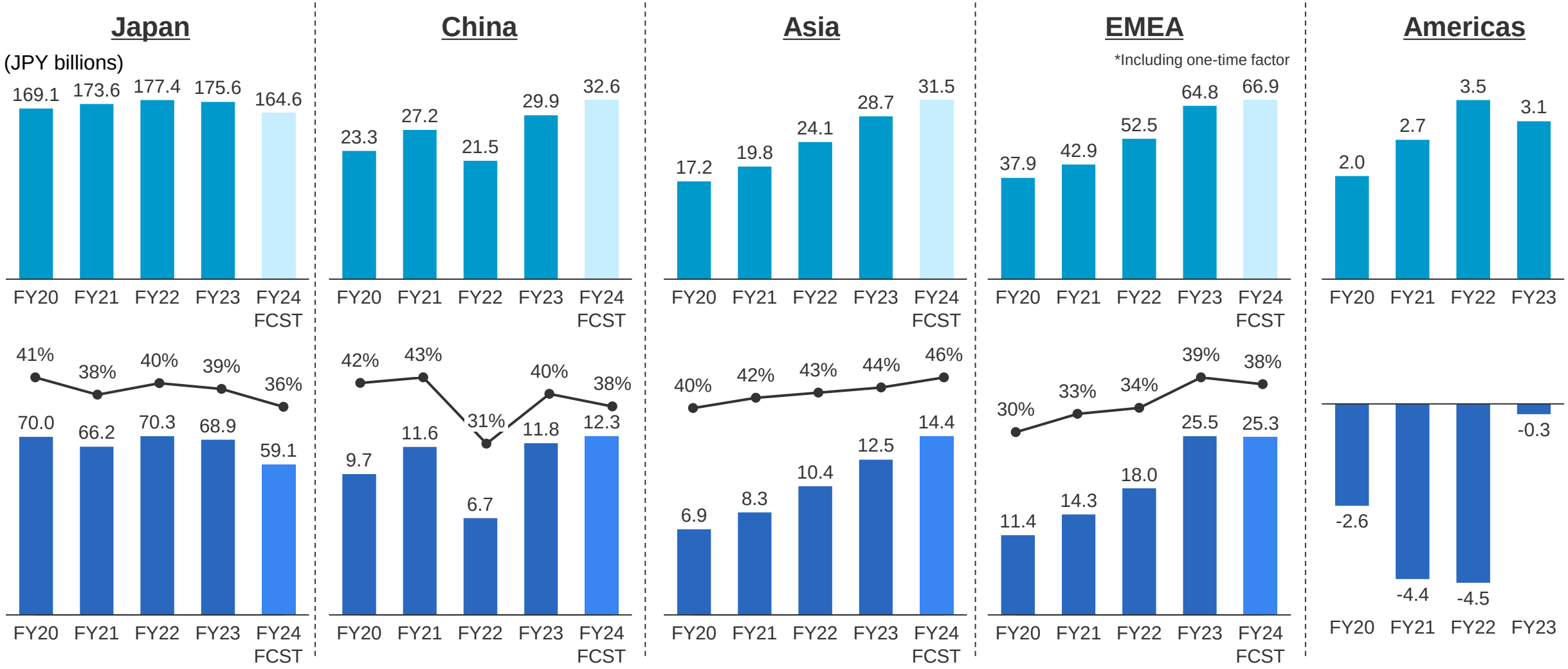


Regional contribution profits	Japan: Decrease in revenue and gross profit due to GEs, NHI price reduction and co-pay hikes for long-listed products, and product mix Overseas: Increase in contribution profit in China and Asia resulting from revenue increase, despite of increase in COGS ratio with cost increase. Including reactionary drop related to *Ikervis*'s one-time factor in FY2023 in EMEA
Others	Completion of structural reforms including streamlining in Americas pharmaceutical commercial business, and promotion of cost optimization. Including company-wide adjustment.

1 R&D and back-office expenses in region and global functions, and contribution profit not related to the regions above

Revenue and contribution profit by region

Upper charts: Revenue (Location basis) Lower charts: Contribution profit, Contribution profit ratio

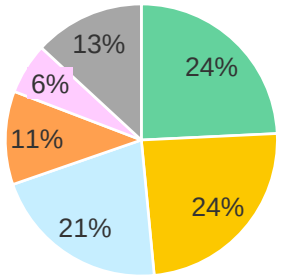


Note) Contribution profit: Deducting cost of sales and expenses related to revenue generation from regional revenue. Regional revenue related to regional business are used to calculate contribution profit and regional revenue may differ from revenue (location basis) in the above chart. In FY2023, there was a large gap between these revenues in Americas because of streamlining and regional revenue to calculate contribution profit was JPY 1.9 billion.
Reorganization in overseas in FY2023 reflects to contribution profits in FY2023 and FY2024 forecast.
Annual impact in FY2023: China JPY 0.5 billion. Asia JPY 0.6 billion, EMEA JPY 2.5 billion.

FY2023 revenue by region

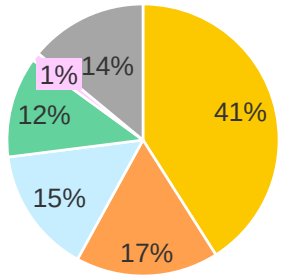
Consolidated

(JPY billions)	FY2022 (Ref.)	FY2023
EYLEA[1]	71.3	72.7
Alesion[2] (Incl. Alesion LX)	33.5	29.5
Diquas (Incl. Diquas LX)	21.0	25.9
Others	153.2	173.9
Total	279.0	302.0



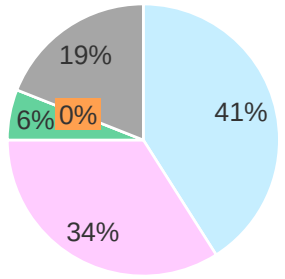
Japan

(JPY billions)	FY2022 (Ref.)	FY2023
EYLEA[1]	71.3	72.7
Alesion[2] (Incl. Alesion LX)	33.4	29.3
Diquas (Incl. Diquas LX)	16.3	20.1
Others	56.5	53.5
Total	177.4	175.6



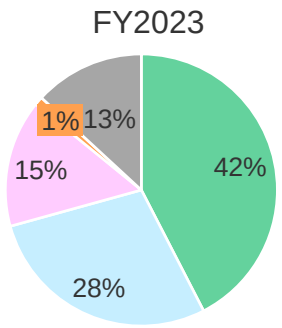
China

(JPY billions)	FY2022 (Ref.)	FY2023
Cravit	6.3	8.8
Hyalein	6.4	8.8
Diquas	2.8	3.3
Others	6.0	8.9
Total	21.5	29.9



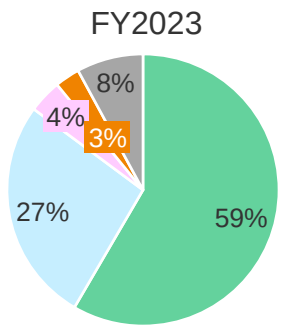
Asia

(JPY billions)	FY2022 (Ref.)	FY2023
Cosopt	6.1	6.9
Cravit	2.4	3.2
Hyalein	2.6	3.1
Others	13.0	15.4
Total	24.1	28.7

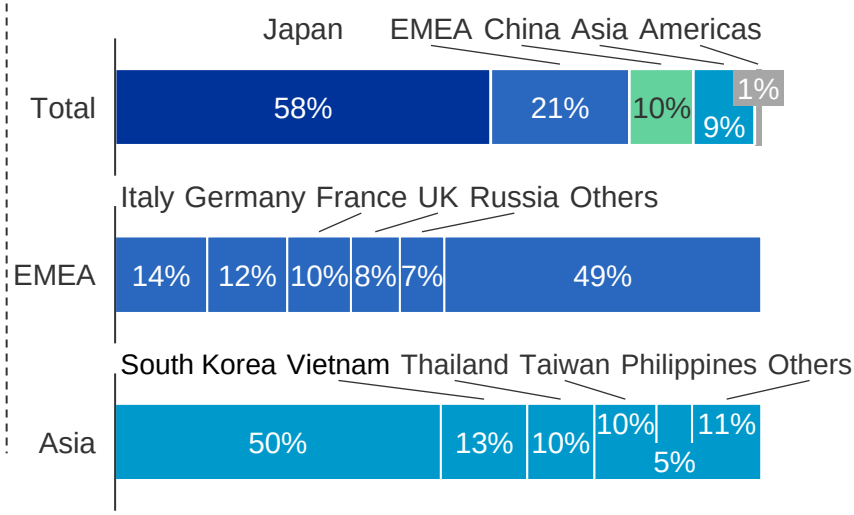


EMEA

(JPY billions)	FY2022 (Ref.)	FY2023
Cosopt	12.9	14.8
Ikervis	5.3	10.2
Tapros	7.7	8.4
Others	26.6	31.4
Total	52.5	64.8



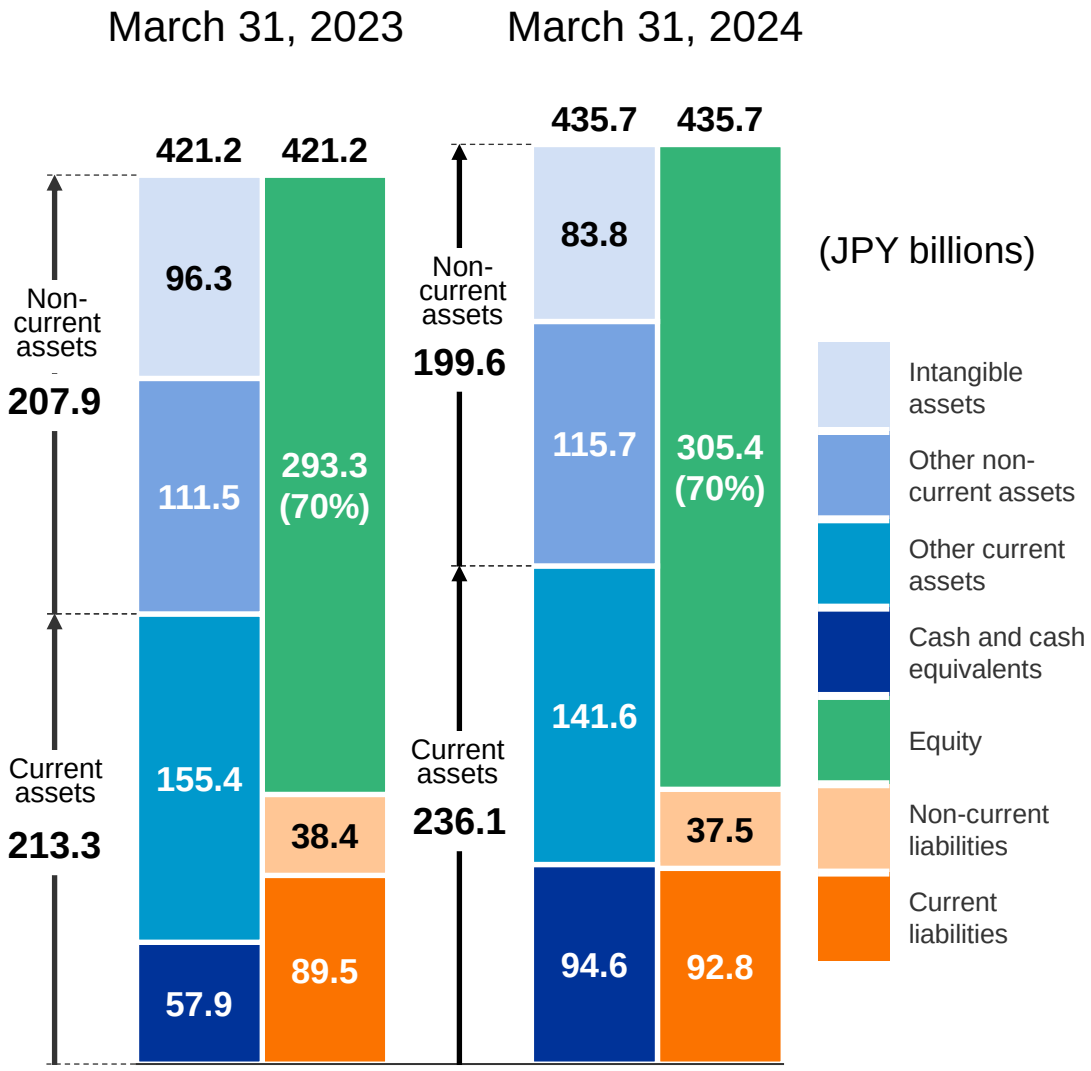
Revenue in each region (FY2023)



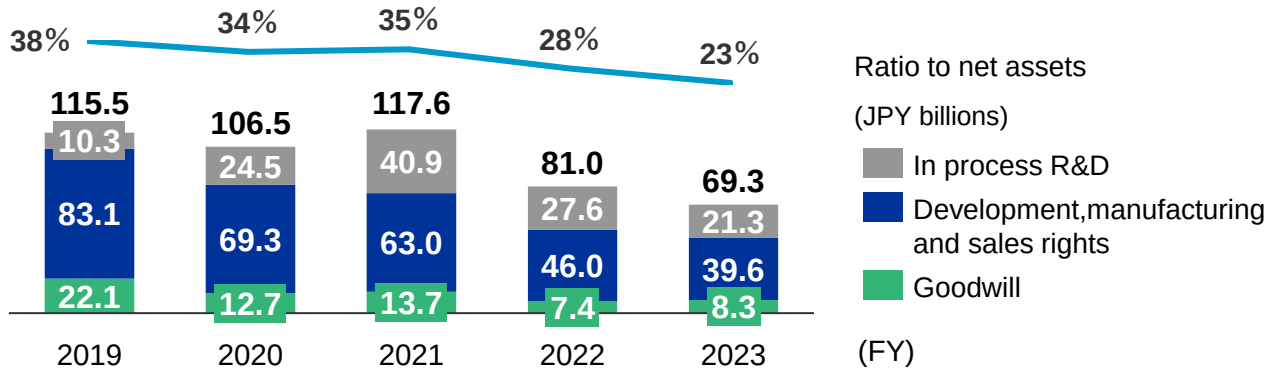
Glaucoma/Device | Intravitreal VEGF inhibitor | Dry eye | Allergy | Bacterial conjunctivitis | Others

1 EYLEA: Co-promoted product of Bayer Yakuhin, Ltd. (MAH)
2 Alesion: Trademark of alliance partner, Nippon Boehringer Ingelheim

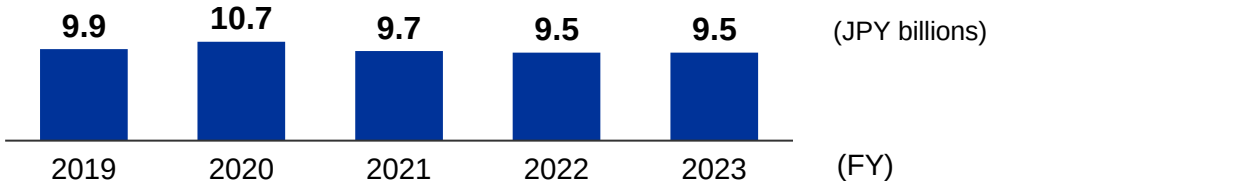
Healthy financial position maintained. Reduce assets to improve ROE, ROIC



Status of intangible assets related to products and goodwill



Status of intangible assets amortization related to products

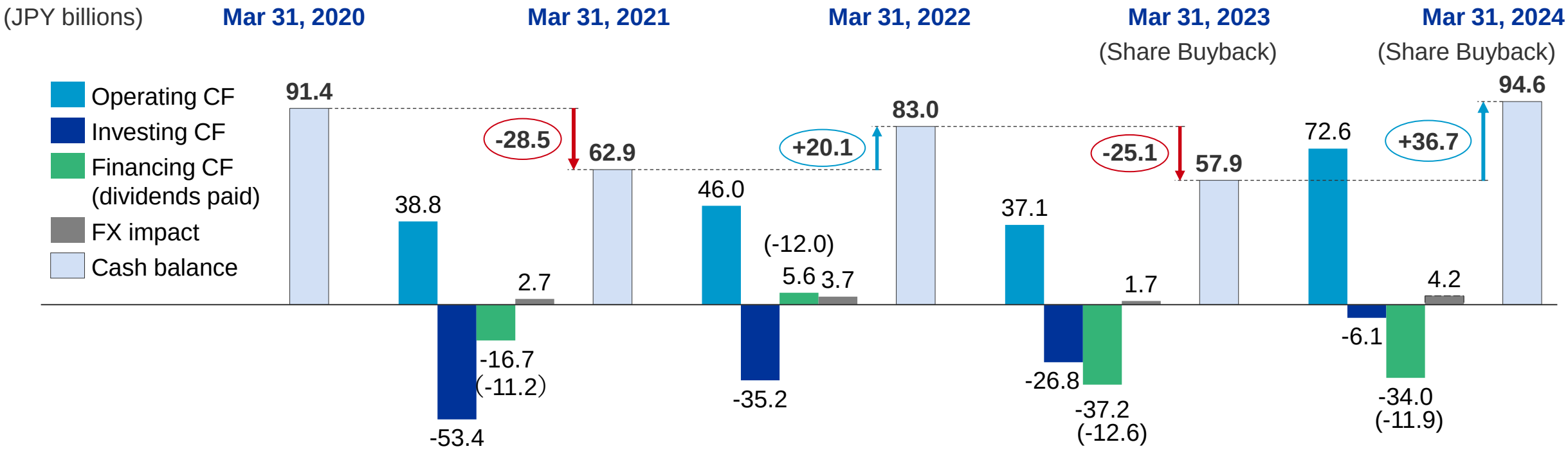


ROE, Core ROE, ROIC

FY	2019	2020	2021	2022	2023	2024 (FCST)
Core ROE	12%	12%	11%	11%	16%	14%[1]
ROE	8%	3%	8%	-	9%	11%[1]
ROIC	11%	5%	12%	-	16%	17%[2]

1 Including share buy-back 2 Including factoring

Cash flow



	FY2019	FY2020	FY2021	FY2022	FY2023
FCF[1] (JPY billions)	30.7	15.0	10.2	12.6	62.0
EBITDA[2] (JPY billions)	56.9	54.8	53.2	49.4	70.5
CCC[3] (Day)	202	220	190	194	167

1 Free cash flow = (Net cash flows from operating activities)-(Capital payments for acquisition of property, plant and equipment, and intangible assets)
2 EBITDA = (Operating Profit)-(Other Income)+(Other expenses)+(Depreciation)
3 Cash conversion cycle: Based on turnover period of trade and other receivables, inventories, and business operation related expenses

Foreign exchange rate assumptions and sensitivities

FX rate

(JPY)

	FY2022 Actual	FY2023 Actual	FY2023 Forecast (Nov.7)	vs FY2023 Forecast	FY2024 Forecast
USD	135.40	144.80	145.00	99.9%	145.00
EUR	140.97	156.88	155.00	101.2%	155.00
CNY	19.72	20.24	20.00	101.2%	20.00

Sensitivities

Impact of a 1% depreciation of the yen (vs FY2024 forecast rate)

(JPY billions)

	Total*	USD	EUR	CNY
Revenue	+1.2	+0.02	+0.62	+0.32
Core OP	+0.1	-0.06	+0.09	+0.06
OP (IFRS)	+0.1	-0.07	+0.07	+0.05

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

FX impact on FY2023 (vs FY2022)

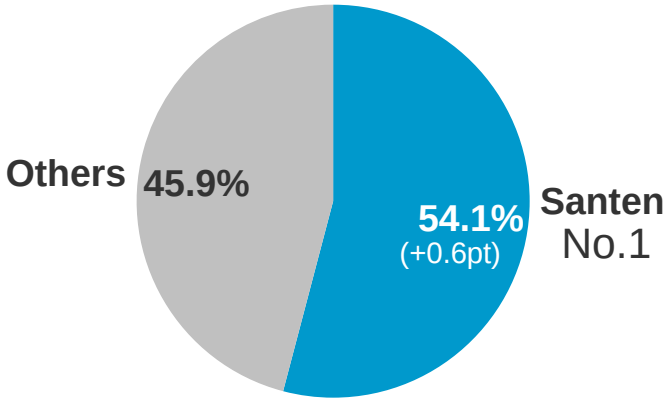
(JPY billions)

	Total
Revenue	+8.5
Core OP	+0.9
OP (IFRS)	-0.2

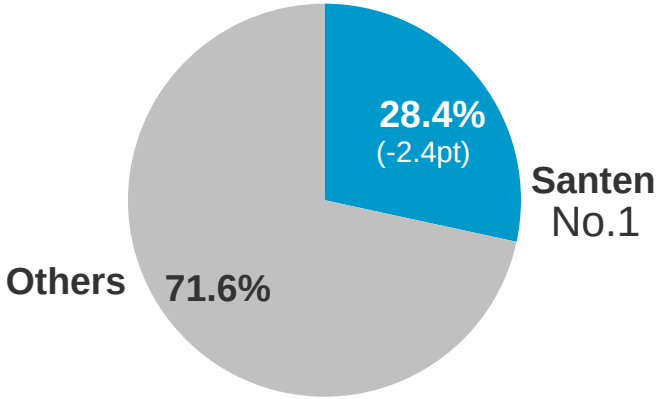
Segment: Market size
Graph: Market share (change from last year)

Prescription Ophthalmic Market in Japan （Apr.2023 - Mar.2024）

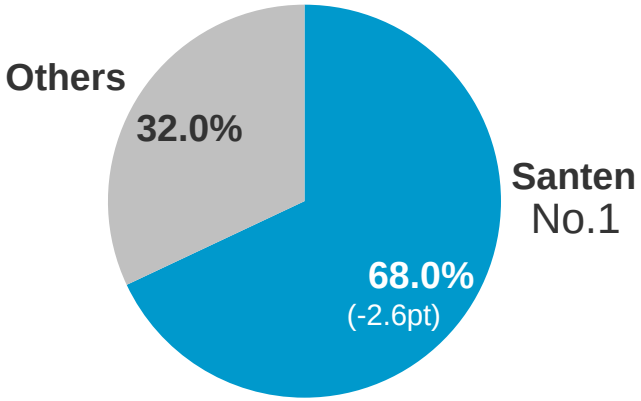
Total: JPY 371.7 bil



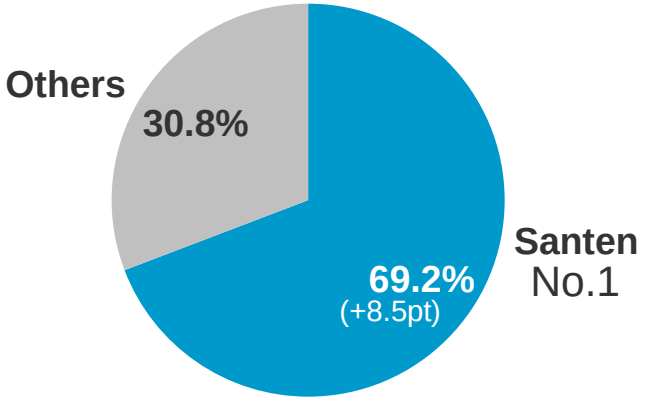
Glaucoma: JPY 88.3 bil



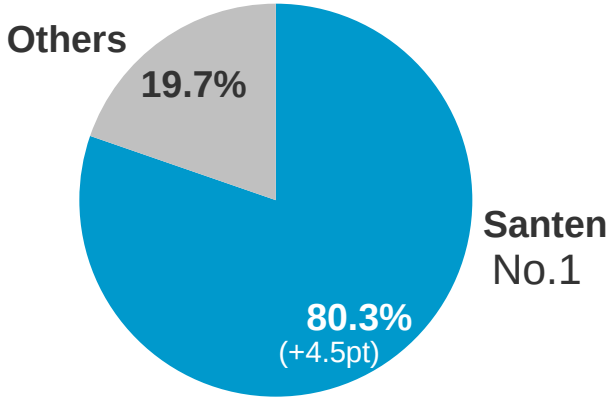
Retinal disorders*: JPY 131.3 bil



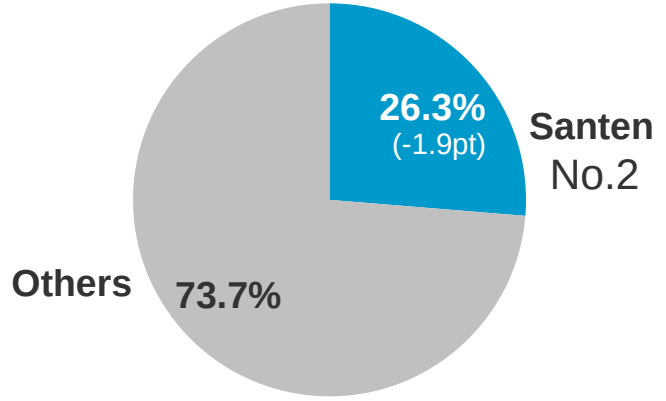
Corneal/dry eye: JPY 48.6 bil



Allergy: JPY 47.8 bil



Anti-infection: JPY 6.6 bil



*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 April 2024
Updated information is in blue

Glaucoma and ocular hypertension area

Indication	Generic Name	Dev. Code	Development Status[1]	
Glaucoma	Tafluprost / timolol maleate (combination) *TAPCOM / TAPTIQOM*	STN10**111**01 DE-111A	China	Filed *Plan: FY2024 approval*
	Sepetaprost	STN10**126**00 DE-126	US	P2 (met primary endpoint)
			Japan	P3 (met primary endpoint) *Plan: FY2024 filing*
			Europe	P2 (exploratory study) completion
	Latanoprost *Catiolanze*	STN10**130**01 DE-130A Catioprost	Europe	Approved *Plan: FY2024 launch*
			Asia	P3 (met primary endpoint) *Plan: FY2024 filing*

1. Only projects for which the study protocols were approved in-house are shown,

Current status of global development (2)

As of April 2024
Updated information is in blue

Glaucoma and ocular hypertension area

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

STN10**117**00 (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 April 2024
Updated information is in blue

Keratoconjunctival disease area including dry eye

Indication	Generic Name	Dev. Code	Development Status	
Vernal keratoconjunctivitis	Ciclosporin *Verkazia*	STN10**076**03[1] DE-076C	China	Approved
Dry eye	Diquafosol sodium (long-lasting) *Diquas LX*	STN10**089**03 DE-089C	Japan	Launched
			Asia	Approved in March 2024 in Korea *Plan: FY2024 launch*
	Olodaterol hydrochloride	STN10**141**00	Japan	P1/2a (met primary endpoint), planning late-stage clinical trials
Fuchs endothelial corneal dystrophy	Sirolimus (eye drop)	STN10**109**04[2]	US France India	P2a *Plan: FY2025 P2a completion*
Meibomian gland dysfunction	Sirolimus (eye drop)	STN10**109**05	Japan	P2a (not met primary/secondary endpoints. But observed efficacy on some exploratory endpoints) *Plan: FY2024 start additional P2a*
Allergic conjunctivitis	Epinastine HCl (eyelid cream)	STN10**114**02	Japan	Approved in March 2024 *Plan: FY2024 launch*
	Epinastine HCl (twice a day, eye drop)	STN10**114**03	China	Started P3 in March 2024 *Plan: FY2025 P3 completion*

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 April 2024
Updated information is in blue

Refractive error

Indication	Generic Name	Dev. Code	Development Status	
Myopia	Atropine sulfate	STN10**127**00 DE-127	Japan	Filed in February 2024 *Plan: FY2024 approval*
			China	P2/3 *Plan: FY2026 P2/3 completion*
			Asia	P2 (met primary endpoint)
		STN10**127**01 SYD-101	Europe	P3 (conducted by Sydnexis Inc.) *Plan: FY2024 P3 completion*
	AFDX0250BS	STN10**134**00	Japan	P2a *Plan: FY2024 P2a completion*
			China	P1 (confirmed safety and tolerability)

The development of ursodeoxycholic acid (STN10**136**00) for the treatment of presbyopia was discontinued following the review of P2a trial data. The company continues R&D activity regarding presbyopia treatment.

Current status of global development (5)

As of April 2024
Updated information is in blue

Others

Indication	Generic Name	Dev. Code	Development Status	
Ptosis	Oxymetazoline hydrochloride	STN10**138**00 RVL-1201	Japan	P3 (met primary endpoint) *Plan: FY2024 filing*
			China	*Plan: FY2024 P3 start*
			Asia	*Plan: FY2026 filing*
Retinitis pigmentosa	jCell	STN**60001**00	-	Planning P3

Q4 FY2023 R&D update

Existing area	Epinastine HCl STN10**114**02 *Alesion* eyelid cream	Allergic conjunctivitis	Received **approval** in Japan
	Diquafosol sodium STN10**089**03 *Diquas LX*	Dry eye	Received **approval** in Asia
	Epinastine HCl (twice a day, eye drop) STN10**114**03	Allergic conjunctivitis	Achieved **FPI**[1] in P3 trial in China
	Olodaterol HCl STN10**141**00	Dry eye	**Achieved primary endpoint** in P1/2a trial in Japan
New area	Atropine sulfate STN10**127**00	Myopia	**Filed** in Japan
	Oxymetazoline HCl STN10**138**00	Ptosis	**Achieved primary endpoint** in P3 trial in Japan
	AFDX0250BS STN10**134**00	Myopia	**Confirmed safety and tolerability** in P1 trial in China

1. FPI; First Patient In

Achieved milestones in existing area and new area as planned

	～Phase 2	Phase 3/filing	Approval/launch
Existing area Glaucoma Dry eye Allergy etc.	Sepetaprost, exploratory study completion STN10**126**00, Europe	Tafluprost/timolol maleate, P3 completion STN10**111**01, China	*Eybelis Mini* (PFUD), approval STN10**117**02, Asia
	Olodaterol HCl, P1/2a completion STN10**141**00, Japan	Sepetaprost, P3 completion STN10**126**00, Japan	*Catiolanze*, approval STN10**130**01, Europe
		Epinastine HCl (twice a day, eye drop), P3 start STN10**114**03, China	*Ducressa*, launch STN10**001**01, Asia
			Cationorm, launch STN10**005**01, China
			Alesion eyelid cream, approval STN10**114**02, Japan
			Alesion LX, approval STN10**114**01, Asia
			Diquas LX, approval STN10**089**03 , Asia
New area Refractive error Ptosis FECD[1] MGD[2] etc.	Sirolimus, decision to conduct additional P2a STN10**109**05, Japan	Oxymetazoline HCl, P3 completion STN10**138**00, Japan	Atropine sulfate, approval STN10**127**00, Japan
	AFDX0250BS, P1 completion China P2a started Japan, STN10**134**00		
	Ursodeoxycholic acid, P2a completion Divelopment discontinued STN10**136**00, US		

- Glaucoma/ocular hypertension
- Keratoconjunctival disease area including dry eye
- Refractive error
- Others

1. Fuchs Endothelial Corneal Dystrophy 2. Meibomian Gland Dysfunction

FY2024~2025 expecting major events about developing pipeline

	FY2024	FY2025
Launch	*Catiolanze* (STN10**130**01, Europe) *Rhopressa* (STN10**139**00, Asia) *Rocklatan* (STN10**140**00, Asia) *Eybelis Mini* (PFUD[1], STN10**117**02, Asia) *Diquas LX* (STN10**089**03, Asia) *Alesion* eyelid cream (STN10**114**02, Japan) *Alesion LX* (STN10**114**01, Asia)	Sepetaprost (STN10**126**00, Japan) Tafluprost/timolol maleate (STN10**111**01, China) Atropine sulfate (STN10**127**00, Japan) Atropine sulfate (STN10**127**01, Europe)
Approval	Tafluprost/timolol maleate (STN10**111**01, China) Atropine sulfate (STN10**127**00, Japan)	Sepetaprost (STN10**126**00, Japan) Oxymetazoline HCl (STN10**138**00, Japan)
Filing	Sepetaprost (STN10**126**00, Japan) Latanoprost cationic emulsion (STN10**130**01, Asia) Oxymetazoline HCl (STN10**138**00, Japan)	Netarsudil mesylate (STN10**139**00, Japan)
Data readout	Netarsudil mesylate P3 long-term (STN10**139**00, Japan) *Confirmed superiority to repasudil AFDX0250BS P2a (STN10**134**00)	Omidenepag isopropyl, PFUD[1] P3 (STN10**117**02, China) Epinastine HCl, twice a day, eye drop P3 (STN10**114**03, China) Sirolimus eye drop, fuchs endothelial corneal dystrophy P2a (STN10**109**04[2]) Sirolimus eye drop, meibomian gland dysfunction additional P2a (STN10**109**05)

The pipelines listed here are only those for which disclosure has been agreed upon with each partner company. Not all planned pipelines or development regions are specified. The schedule is based on the best-case scenario assumed as of March 31, 2024, and does not guarantee launch. 1 Preservative Free Unit Dose 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.

Expected launch schedule

: LCM products
: Drug with a new active ingredient/Medical device

		FY2024	FY2025	FY2026~
Existing area[1]	Glaucoma	***Catiolanze*** EMEA ***Rhopressa*** Asia ***Eybelis* PFUD**[5] Asia ***Rocklatan*** Asia	STN10**126**00 JP ***Taptiqom*, PFUD** CN	***Eybelis* PFUD** CN ***Roclanda* PFMD** EMEA STN10**126**00 CN, EMEA **MicroShunt** CN ***Catiolanze* PFMD**[6] EMEA ***Rocklatan*** JP ***Catiolanze*** Asia ***Rhopressa*** JP
	Dry eye	***Diquas LX*** Asia		***Diquas LX*** CN STN10**14**00 Worldwide (WW)
	Allergy	***Alesion LX*** Asia ***Alesion* eyelid cream** JP		***Alesion LX*** CN
New area[2]	Myopia		STN10**127**00 JP STN10**12701** EMEA	STN10**127**00 CN, Asia STN10**134**00 WW
	Ptosis			STN10**138**00 JP, CN, Asia, EMEA
	FECD[3]			STN10**10904**[7] **(FECD)**
	MGD[4]			STN10**10905 (MGD)** WW
	Retinitis pigmentosa			**jCell** JP, CN, Asia, EMEA

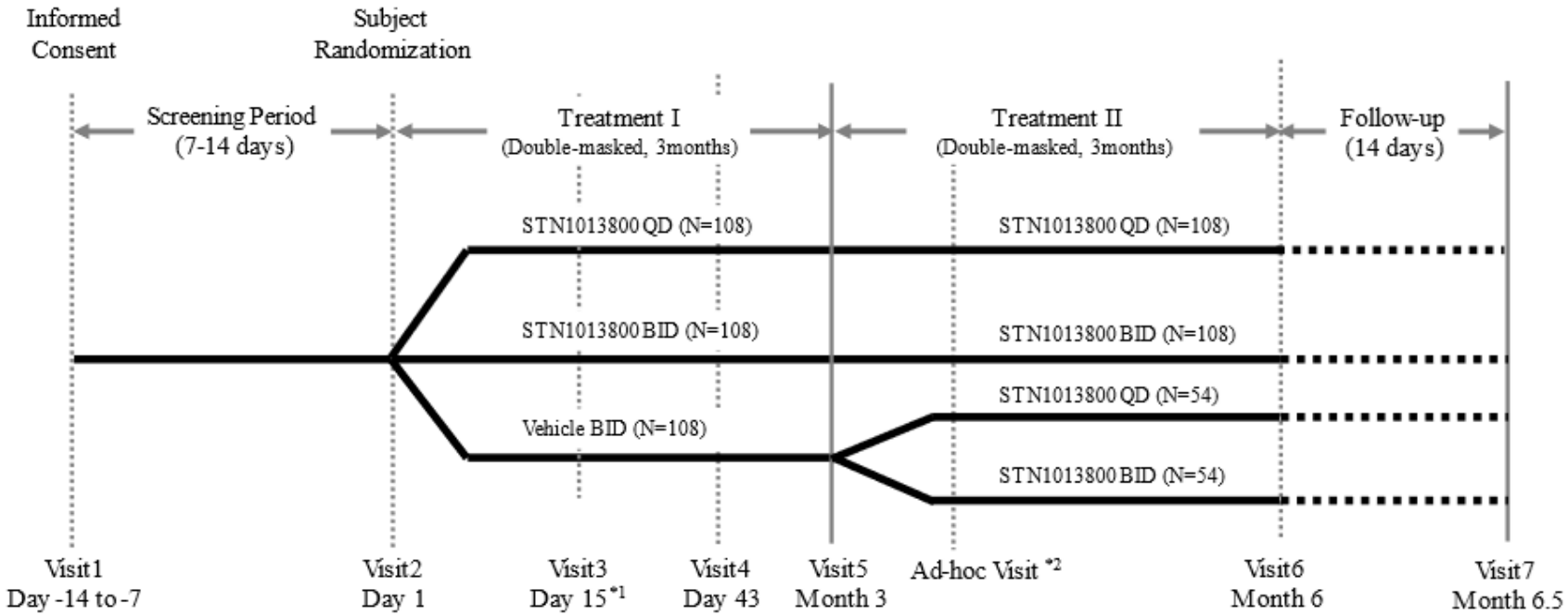
The pipelines listed here are only those for which disclosure has been agreed upon with each partner company. Not all planned pipelines or development regions are specified. The schedule is based on the best-case scenario assumed as of March 31, 2024, and does not guarantee launch. 1. Disease areas where our existing products already obtained indications. 2. Disease areas where there are no existing Santen products on the market with indications. 3. Fuchs Endothelial Corneal Dystrophy 4. Meibomian Gland Dysfunction 5. Preservative Free Unit Dose 6. Preservative Free Multi Dose 7. Santen holds the exercise option for exclusive implementation rights for this program. This project code is a planned code number that will be assigned after Santen obtains exclusive implementation rights upon completion of Phase II clinical trials

P3 trial protocol in Japan

jRCT2031220394:https://jrct.niph.go.jp/latest-detail/jRCT2031220394

A Multicenter, Randomized, Confirmatory, Double-Masked, Placebo-Controlled Parallel Group Phase III

Primary endpoint: change from Hour 0 at Day 1 for MRD-1 at Day 15 Hours 2 after the first instillation for **QD (once a day)** and **BID (twice a day)**



STN1013800 QD : One drop in each eye, in the morning (active) and afternoon (placebo)
STN1013800 BID : One drop in each eye, in the morning (active) and afternoon (active)
Vehicle BID : One drop in each eye, in the morning (placebo) and afternoon (placebo)

*1 Primary efficacy endpoint
*2 In case that investigator judges to set rest-of-drug period during Visit5 (Month3), the ad-hoc visit at 14days (±3days) after start of rest -of-drug period will be arranged.

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.
- This document contains information about pharmaceutical products (including products under development) but is not intended for advertising or medical advice.
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