# Q3 FY2023 Financial Results

February 8, 2024

**Santen Pharmaceutical Co., Ltd.**

# Financial Results

**Kazuo Koshiji**

Chief Financial Officer &

Chief Risk Officer

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

| | Q3 FY2022 ACT | Q3 FY2023 ACT |
|---|---|---|
| USD (JPY) | 136.22 | 143.61 |
| EUR (JPY) | 140.43 | 155.60 |
| CNY (JPY) | 19.86 | 20.07 |

| (JPY billions) | Q3 FY2022 | | Q3 FY2023 | | | FY2023 | |
|---|---|---|---|---|---|---|---|
| | Actual | vs Revenue | Actual | vs Revenue | YoY | Forecast Nov. 7 | vs Revenue |
| **Revenue** | 199.8 | - | **222.8** | **-** | **+11.5%** | 302.0 | - |
| Cost of sales | 85.4 | 43% | 91.4 | 41% | +7.0% | 121.0 | 40% |
| **Gross profit** | 114.3 | 57% | **131.4** | **59%** | **+14.9%** | 181.0 | 60% |
| SG&A expenses | 65.5 | 33% | 64.1 | 29% | -2.2% | 94.0 | 31% |
| R&D expenses | 21.7 | 11% | 18.0 | 8% | -16.7% | 29.0 | 10% |
| **Core operating profit** | 27.2 | 14% | **49.3** | **22%** | **+81.5%** | 58.0 | 19% |
| Non-core expenses | - | - | 1.0 | 0% | - | 1.1 | 0% |
| Amortization on intangible assets associated with products | 7.2 | 4% | 7.1 | 3% | -2.0% | 9.4 | 3% |
| Other income | 0.5 | 0% | 1.4 | 1% | +161.3% | 1.5 | 0% |
| Other expenses | 30.6 | 15% | 6.4 | 3% | -79.1% | 8.0 | 3% |
| **Operating profit** | -10.1 | - | **36.2** | **16%** | **-** | 41.0 | 14% |
| Finance income | 1.0 | 0% | 1.3 | 1% | +32.0% | 1.5 | 0% |
| Finance expenses | 0.7 | 0% | 1.0 | 0% | +38.4% | 1.2 | 0% |
| Share of loss of investments accounted for using equity method | 1.7 | 1% | 2.9 | 1% | +69.2% | 3.0 | 1% |
| Profit before tax | -11.6 | - | 33.6 | 15% | - | 38.3 | 13% |
| Income tax expenses | 4.5 | 2% | 7.0 | 3% | +55.3% | 8.8 | 3% |
| *Actual tax ratio* | - | - | *20.8%* | - | - | *23%* | - |
| **Net profit** | -16.1 | - | **26.6** | **12%** | **-** | 29.5 | 10% |
| Core net profit | 21.2 | 11% | 39.6 | 18% | +87.2% | 43.5 | 14% |

## Gross margin

**+14.9% YoY**

- Revenue: Strong progress mainly from overseas YoY: +11.5% (consolidated), +25% (overseas) (Including one-time factors in H1[*1])
- COGS: Ratio decrease excluding above-mentioned one-time factors from region/product mix

## Operating profit (Core basis)

**+81.5% YoY**

- Improved Core OP ratio. Reduced SG&A from cost optimization, personnel costs reduction by structural reforms and offset foreign-currency denominated expenses increase from weaker JPY

## Operating profit (IFRS)

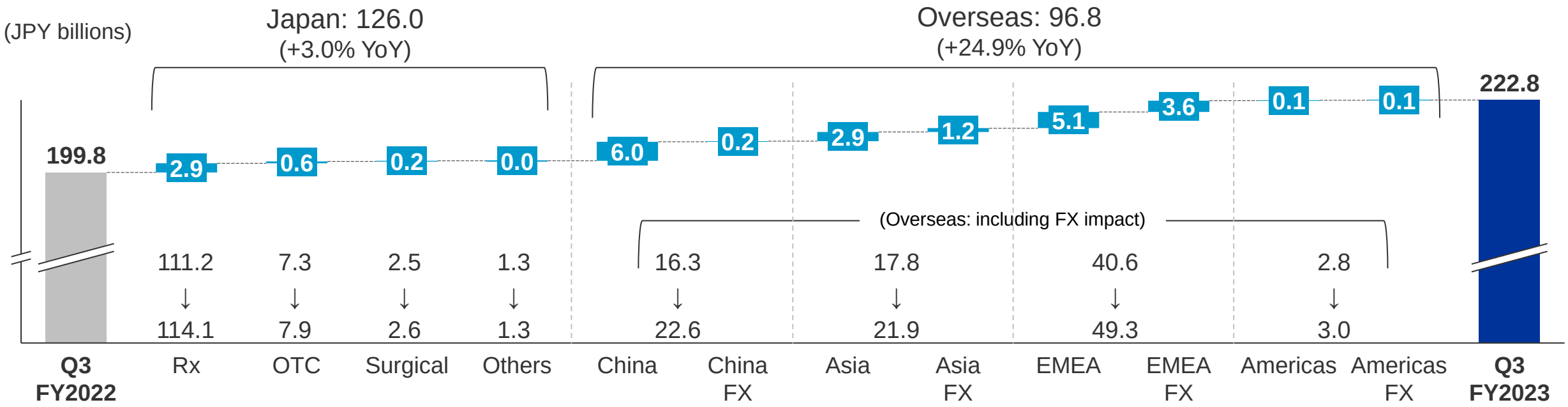
- Other income: Upfront related to Americas of JPY 0.7 billion[*2]
- Structural reforms cost: JPY 6.8 billion (non-core expenses and other expenses)

## Net profit (IFRS)

- Tax ratio excluding one-time factors including impairment loss in FY2022 and structural reforms: 24.1% (FY2022), 20.6% (FY2023)

*1: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 *2: Asset transfer to Harrow Health (USD 5 million), H1

# YoY sales growth of +9.0% (excluding FX impact) mainly driven by Overseas



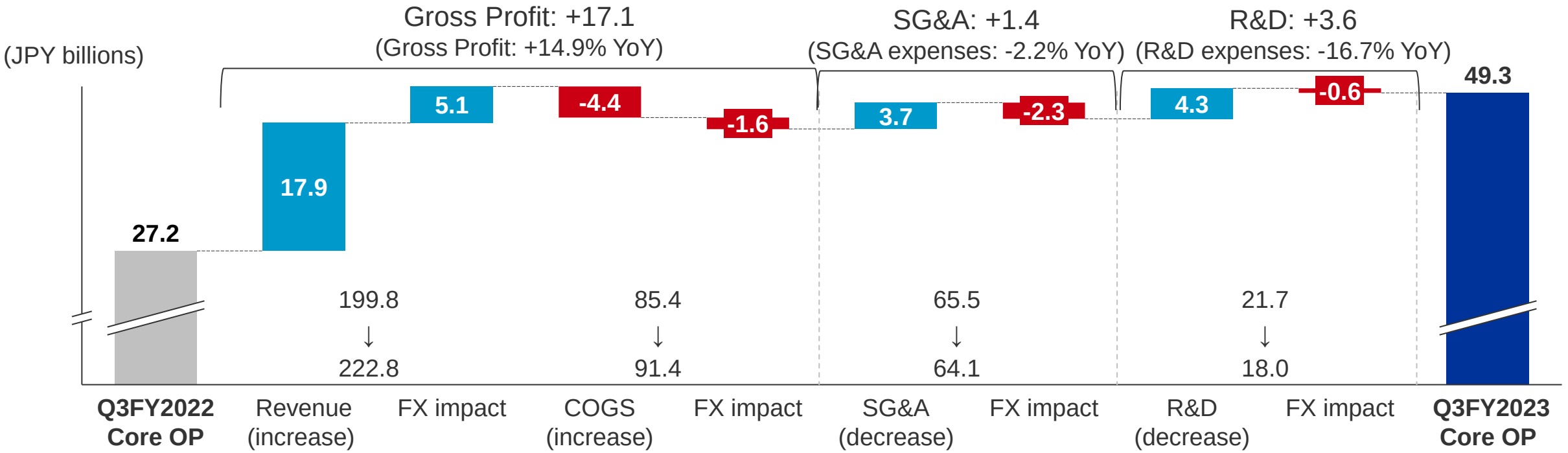

| | |
|---|---|
| Japan | +3.0% YoY: Growth from mainstay products |
| China | +38.3% YoY (Ex. FX impact +36.9%): Strong performance from multi-channel strategy coupled with market recovery from COVID-19 |
| Asia | +23.2% YoY (Ex. FX impact +16.4%): Steady growth from mainstay products in key markets.<br>Including impact of shipment timing and high-demand related to infection products in Vietnam |
| EMEA | +21.5% YoY (Ex. FX impact +12.7%): Continued growth in glaucoma products and *Ikervis* for dry eye in EU5 and Nordic.<br>Including *Ikervis* one-time impact |
| Americas | +7.2% YoY (Ex. FX impact +3.6%): 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

Q3 FY2023 Core OP bridge

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




| | |
|---|---|
| Gross profit | Net JPY +17.1 billion YoY. Increased revenue (+11.5% YoY including FX, +9.0% YoY excluding FX) and decrease in COGS ratio (42.8% to 41.0%) resulting from region/product mix and one-time factors |
| SG&A | Net JPY +1.4 billion YoY. SG&A ratio significantly decreased resulting from cost optimization and structural reforms including personnel expenses reduction (SG&A ratio: 32.8% to 28.7%). Absorbed increased foreign-currency based expenses from a weaker JPY |
| R&D | Net JPY +3.6 billion YoY. Mainly from development schedule change in certain projects and timing of expense recognition (R&D expenses ratio: 10.9% to 8.1%). No change for policy to prioritize investment to R&D |

FY2023 Outlook

# No change from November 7
# 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 | | |
|---|---|---|---|---|---|
| | Actual | vs Revenue | Forecast Nov.7 | vs Revenue | YoY |
| **Revenue** | 279.0 | - | **302.0** | **-** | **+8.2%** |
| Cost of sales | 113.0 | 40% | 121.0 | 40% | +7.1% |
| **Gross profit** | 166.1 | 60% | **181.0** | **60%** | **+9.0%** |
| SG&A expenses | 93.5 | 34% | 94.0 | 31% | +0.5% |
| R&D expenses | 28.3 | 10% | 29.0 | 10% | +2.5% |
| **Core operating profit** | 44.2 | 16% | **58.0** | **19%** | **+31.1%** |
| Non-core expenses | 2.7 | 1% | 1.1 | 0% | -59.4% |
| Amortization on intangible assets associated with products | 9.5 | 3% | 9.4 | 3% | -1.2% |
| Other income | 3.5 | 1% | 1.5 | 0% | -57.4% |
| Other expenses | 38.6 | 14% | 8.0 | 3% | -79.3% |
| **Operating profit** | -3.1 | - | **41.0** | **14%** | **-** |
| Finance income | 1.2 | 0% | 1.5 | 0% | +30.1% |
| Finance expenses | 1.5 | 1% | 1.2 | 0% | -19.9% |
| Share of loss of investments accounted for using equity method | 2.4 | 1% | 3.0 | 1% | +27.0% |
| Profit before tax | -5.8 | - | 38.3 | 13% | - |
| Income tax expenses | 9.2 | 3% | 8.8 | 3% | -4.2% |
| *Actual tax ratio* | - | - | *23%* | - | - |
| **Net profit** | -15.0 | - | **29.5** | **10%** | **-** |
| ROE | - | | 10% | | |
| Core ROE | 10.5% | | 15% | | |
| Core net profit | 33.2 | 12% | 43.5 | 14% | +30.9% |

## Factors to consider

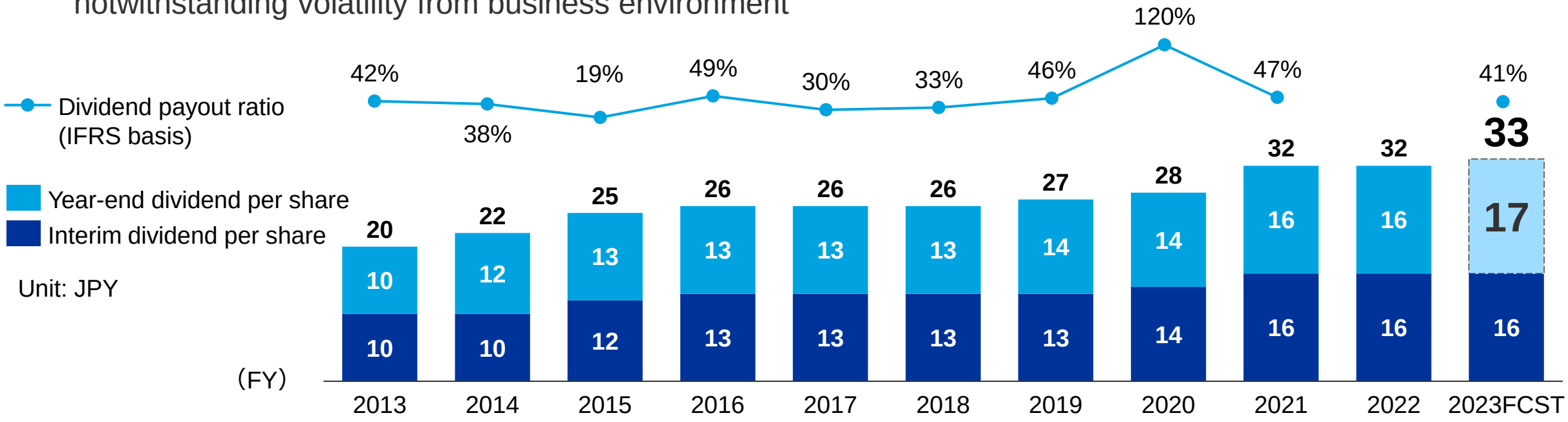
- Japan: Pollen-levels
- Overseas: Macro environment

- 2024 Noto Peninsula Earthquake
  No material business impact expected

# Increase annual dividend forecast to JPY33 on the back of completion of structural reforms and clarity on medium to long-term sustainable profit levels

## Medium-term management plan dividend policy：

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




| | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023FCST |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Total return ratio (IFRS basis) | 42% | 38% | 19% | 106% | 30% | 76% | 46% | 120% | 47% | - | 124% |
| Share buy-back (JPY billions) | - | - | - | 12.3 | - | 13.9 | - | - | - | 25.7 | 24.5 (max.) |
| ROE (Core basis) | 11% | 13% | 12% | 11% | 12% | 13% | 12% | 12% | 11% | 11% | 15% |

# R&D Update

**Peter Sallstig**

Chief Medical Officer

# *Catiolanze* (STN1013001) approval in Europe
# Preparations kick start for additional P2a trial of sirolimus eye drop to MGD[1]

| | | | |
|---|---|---|---|
| **Existing area** | *Catiolanze*<br>STN10**13**001<br>Latanoprost cationic emulsion | Glaucoma | Received **approval** in Europe |
| | Olodaterol HCl<br>STN10**14**100 | Dry eye | Achieved **LPO**[2] in P1/2a trial in Japan |
| **New area** | Oxymetazoline HCl<br>STN10**138**00 | Ptosis | Achieved **LPO** in P3 trial in Japan<br>Updated development schedule<br>China: Plan to start P3 trial in FY2024, Asia: Plan to file in FY2026 |
| | AFDX0250BS<br>STN10**134**00 | Myopia | Achieved **LPI**[3] in P2a trial in Japan |
| | Sirolimus eye drop<br>STN10**109**04[4] | Fuchs endothelial corneal dystrophy | Achieved **LPI** in P2a trial in US, France and India |
| | Sirolimus eye drop<br>STN10**109**05 | Meibomian gland dysfunction | **Started preparations for additional P2a trial** in Japan |
| | Ursodeoxycholic acid<br>STN10**136**00 | Presbyopia | Discontinued development following the review of P2a trial data<br>(Continuing R&D activity regarding presbyopia treatment) |

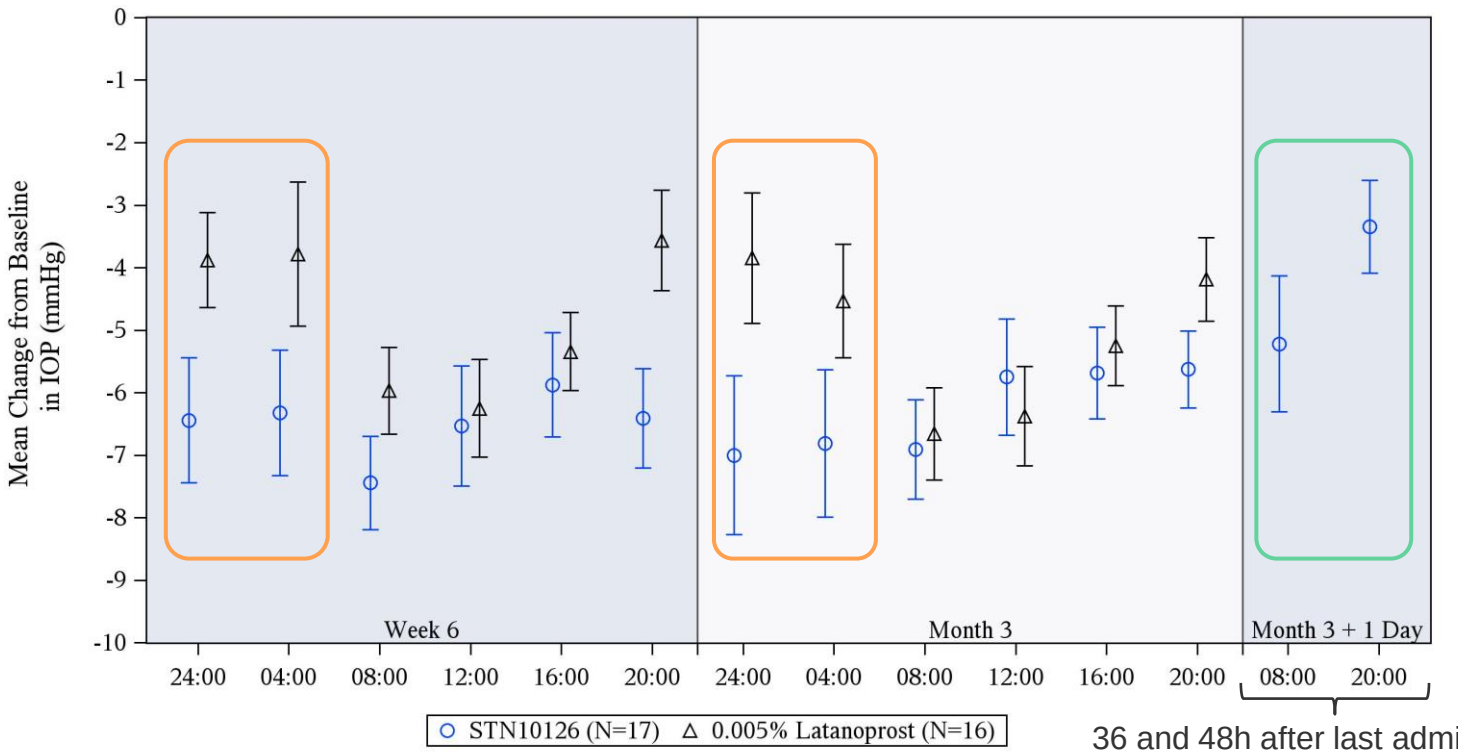


1. Meibomian gland dysfunction 2. Last Patient Out 3. LPI; Last Patient In 4. Santen retains the option right for exclusive license of this program. Santen development code to be formally assigned to the product when Santen obtains exclusive license upon the completion of Phase II trial.

# Investigated IOP for/over 24h in P2 (exploratory study) in Europe

*This study was not adequately powered, and statistical sample size wasn't designed.
*This was conducted in preservative-free formulation (STN1012601).

- **Intraocular pressure change (IOP, mmHg)**




36 and 48h after last administration

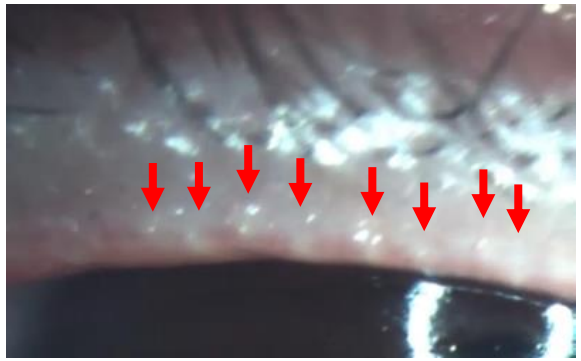
- A numerically higher lowering effect than latanoprost was observed in nocturnal IOP at week 6 and month 3.
- At 36 and 48 hours after administration, the IOP decreased by 3 to 5 mmHg compared with time-matched baseline.
- Plan to submit in Japan in FY2024 with a pivotal study data that achieved the primary endpoint (disclosed at Q2 FY2023 briefing meeting).

# Planning additional P2a trial to investigate improvement in the obstruction of meibomian gland based on findings from previous P2a trial

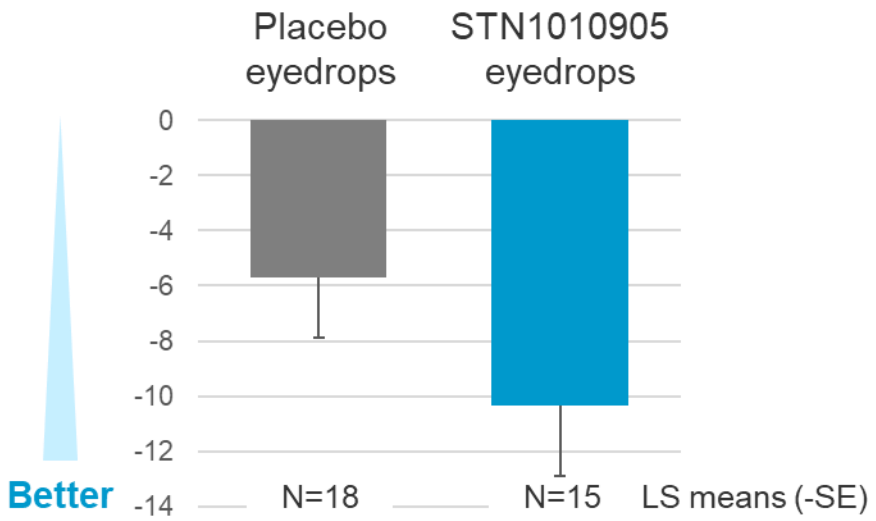
Previous P2a trial

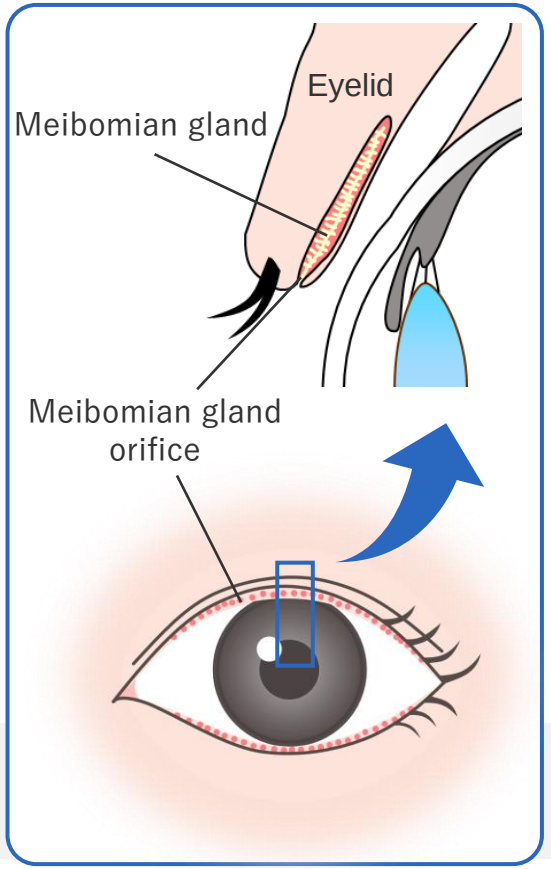
- Primary endpoint : Obstruction grading score of meibomian gland orifice was set based on literature because of new disease area, however, it was not achieved
- Exploratory endpoint : Post-hoc analysis suggested an improvement over the placebo group in the number of obstructed meibomian gland orifices

**Meibomian gland orifice obstruction**



**Change from baseline in the No. of obstructed meibomian gland orifices**

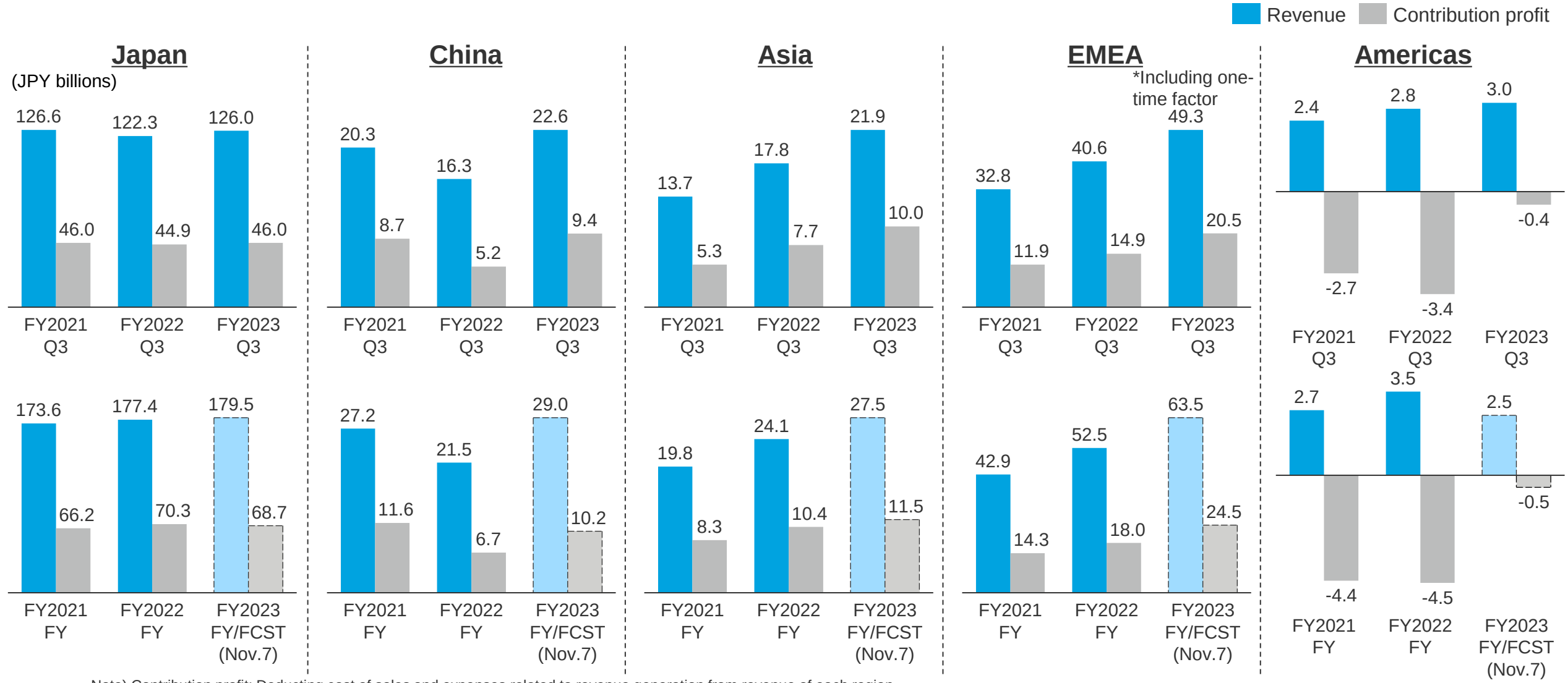



- Planning to initiate an additional P2a trial in FY2024 using the number of meibomian gland obstruction as a new efficacy endpoint

# Appendix

# Revenue and contribution profit by region



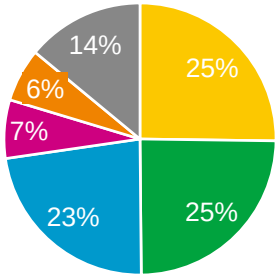

Note) Contribution profit: Deducting cost of sales and expenses related to revenue generation from revenue of each region.
Due to reorganization in Asia and EMEA in Q2 FY2023, contribution profits in Asia and EMEA in FY2023 are revised retroactively (Annual impact: Asia JPY 0.7 billion, EMEA JPY 2.3 billion). This change is included in FY2023 revised forecast on November 7.
In Q3, same reorganization was taken in China. Annual impact is JPY 0.6 billion and is not included in the annual forecast. No impact to consolidated numbers.

# Q3 FY2023 revenue by region

## Consolidated

| (JPY billions) | Q3 FY2022 (Ref.) | Q3 FY2023 |
|---|---|---|
| EYLEA*1 | 54.7 | 56.2 |
| Diquas (Incl. Diquas LX) | 15.7 | 21.1 |
| Cosopt | 18.1 | 19.2 |
| Others | 111.3 | 126.3 |
| Total | 199.8 | 222.8 |

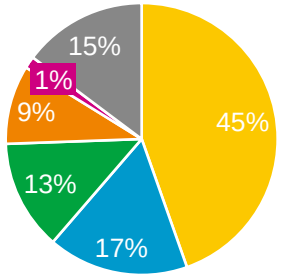
Q3 FY2023




## Japan

| (JPY billions) | Q3 FY2022 (Ref.) | Q3 FY2023 |
|---|---|---|
| EYLEA*1 | 54.7 | 56.2 |
| Diquas (Incl. Diquas LX) | 12.1 | 16.4 |
| Alesion*2 (Incl. Alesion LX) | 12.0 | 11.5 |
| Others | 43.5 | 41.9 |
| Total | 122.3 | 126.0 |

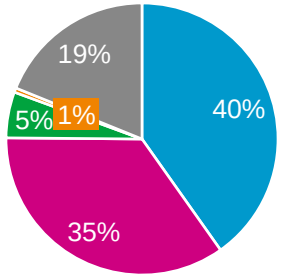
Q3 FY2023




## China

| (JPY billions) | Q3 FY2022 (Ref.) | Q3 FY2023 |
|---|---|---|
| Cravit | 4.3 | 7.0 |
| Hyalein | 5.0 | 6.3 |
| Diquas | 2.2 | 2.8 |
| Others | 4.9 | 6.5 |
| Total | 16.3 | 22.6 |

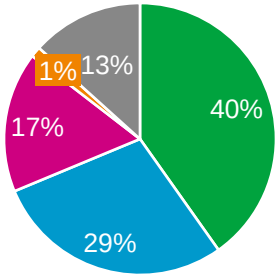
Q3 FY2023




## Asia

| (JPY billions) | Q3 FY2022 (Ref.) | Q3 FY2023 |
|---|---|---|
| Cosopt | 4.5 | 5.1 |
| Cravit | 1.8 | 2.7 |
| Hyalein | 2.2 | 2.5 |
| Others | 9.4 | 11.7 |
| Total | 17.8 | 21.9 |

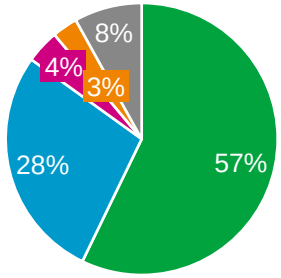
Q3 FY2023



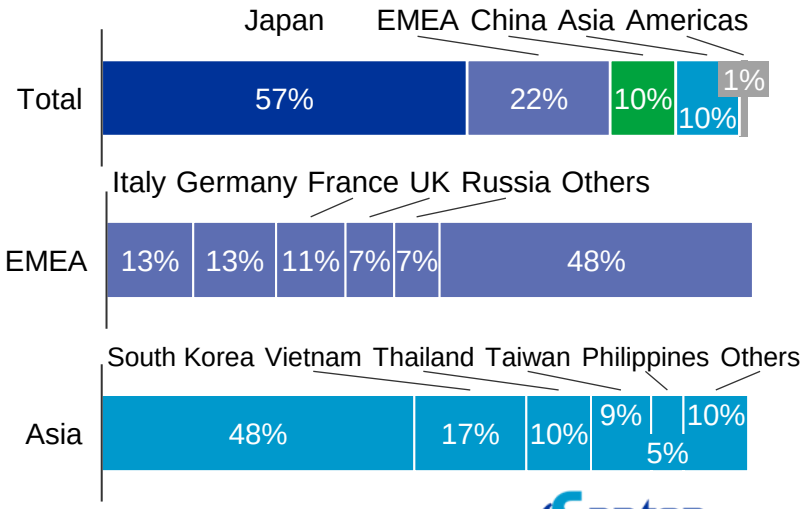

## EMEA

| (JPY billions) | Q3 FY2022 (Ref.) | Q3 FY2023 |
|---|---|---|
| Cosopt | 9.9 | 10.9 |
| Ikervis | 4.3 | 8.4 |
| Tapros | 6.0 | 6.2 |
| Others | 20.4 | 23.8 |
| Total | 40.6 | 49.3 |

Q3 FY2023




## Revenue in each region (Q3 FY2023)



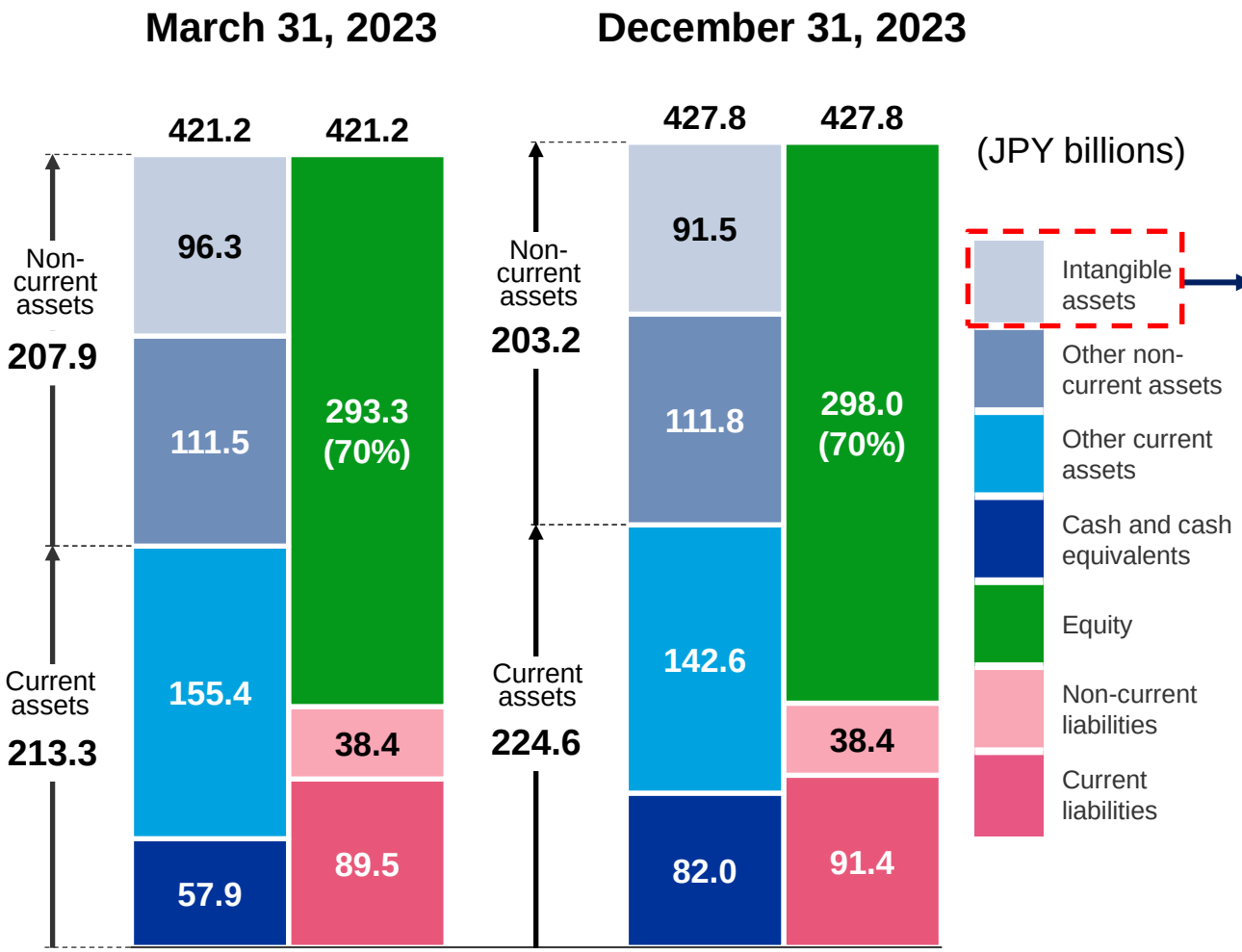

Intravitreal VEGF inhibitor / Glaucoma/Device / Dry eye / Bacterial conjunctivitis / Allergy / Others



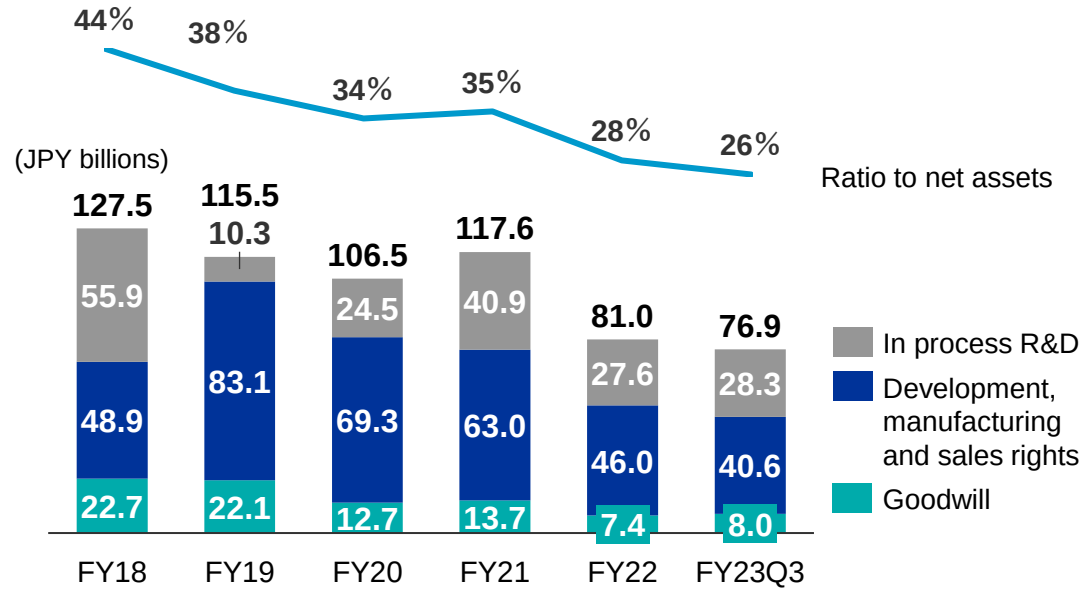
*1EYLEA: Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

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

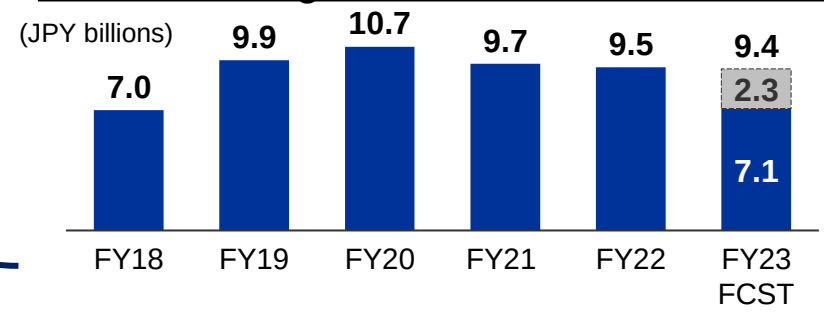
# Healthy financial position maintained. Reduce assets to improve ROE, ROIC



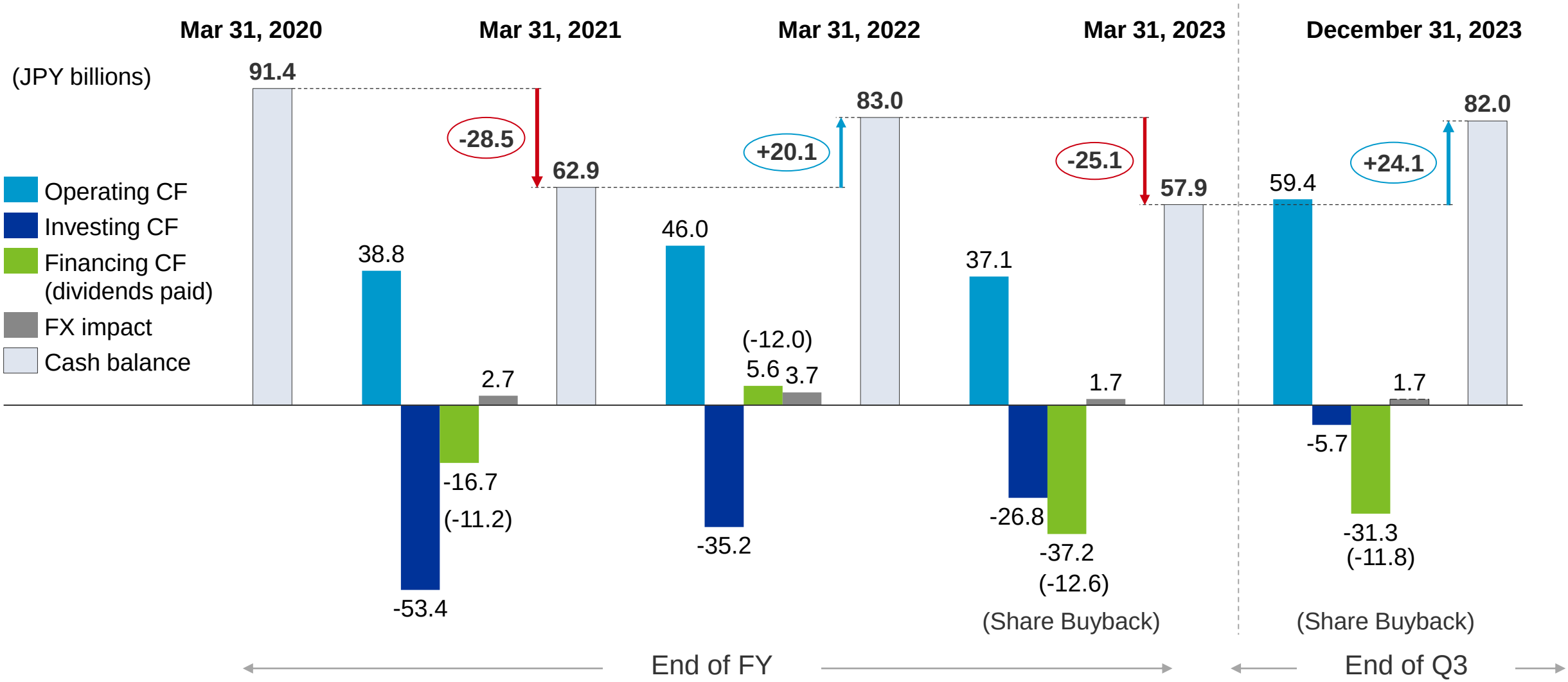

## Status of intangible assets related to products and goodwill




## Status of intangible assets amortization related to products



# Cash flow



# Foreign exchange rate assumptions and sensitivities

## FX rate

(JPY)

| | Q3 FY2022 Actual | Q3 FY2023 Actual | FY2023 FCST (Nov. 7) | Vs FY2023 FCST (Nov. 7) | FY2022 Actual |
|---|---|---|---|---|---|
| USD | 136.22 | 143.61 | 145.00 | 99.0% | 135.40 |
| EUR | 140.43 | 155.60 | 155.00 | 100.4% | 140.97 |
| CNY | 19.86 | 20.07 | 20.00 | 100.4% | 19.72 |

## 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 |

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

FX impact on Q3 FY2023 (vs Q3 FY2022)

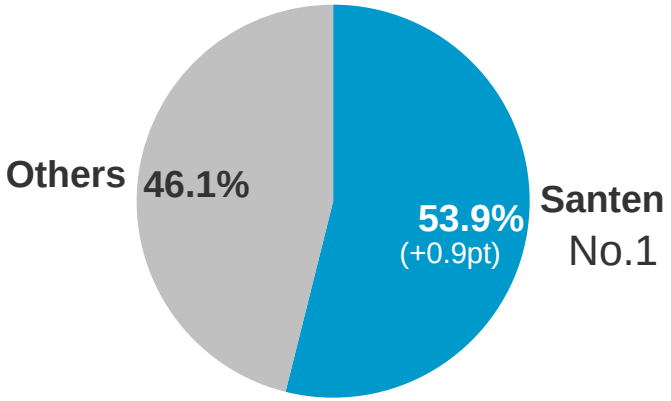
(JPY billions)

| | Total |
|---|---|
| Revenue | +5.1 |
| Core OP | +0.6 |
| OP (IFRS) | +0.3 |

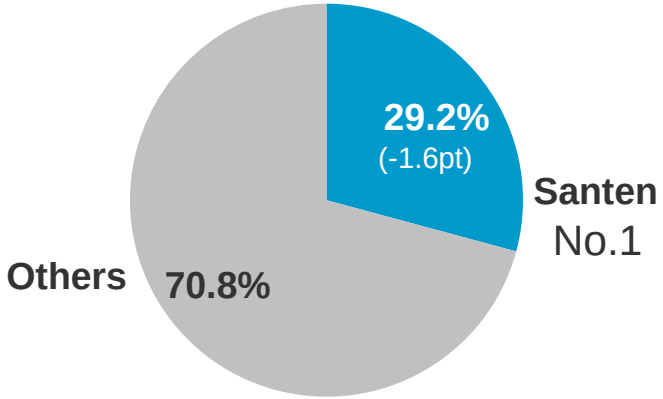
Segment: Market size
Graph: Market share (change from last year)

# Prescription Ophthalmic Market in Japan （Jan.2023 - Dec.2023）

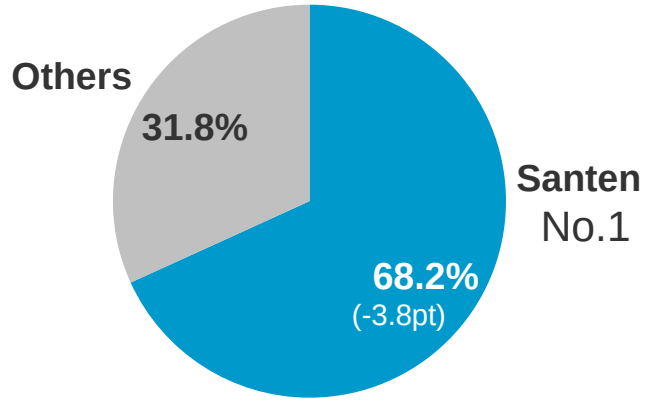
## Total: JPY376.7bil



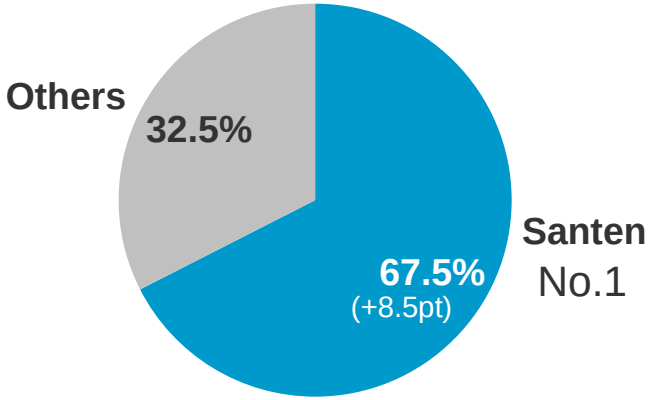

## Glaucoma: JPY89.7bil



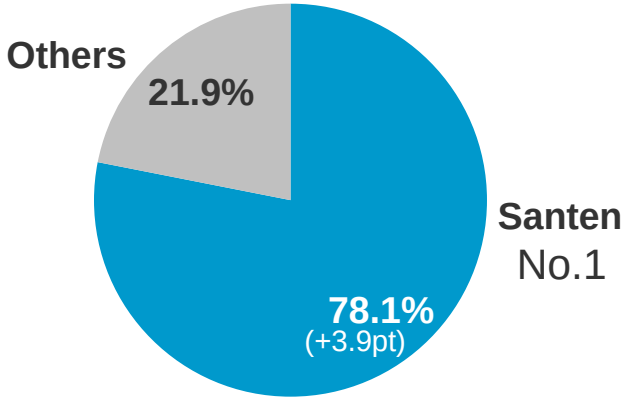

## Retinal disorders*: JPY130.2bil



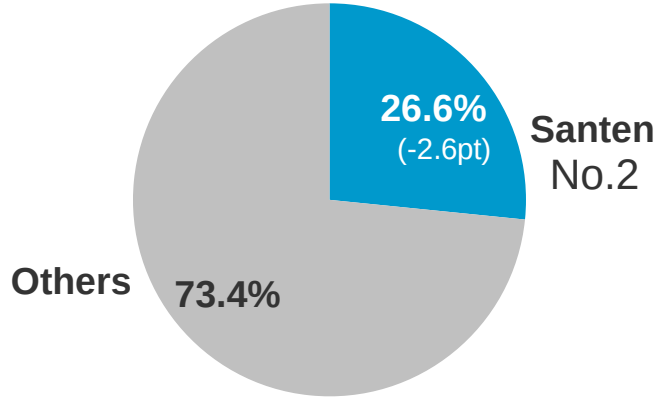

## Corneal / dry eye: JPY48.7bil




## Allergy: JPY51.8bil




## 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 January 2024
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)<br>*TAPCOM / TAPTIQOM* | Japan, China Asia, Europe | STN10**11**101<br>DE-111A | China | Filed<br>*Plan: FY2024 approval* |
| | Sepetaprost | WW[2] | STN10**126**00<br>DE-126 | US | P2 (met primary endpoint) |
| | | | | Japan | P3 (met primary endpoint)<br>*Plan: FY2024 filing* |
| | | | | Europe | P2 (exploratory study) completion |
| | Latanoprost<br>*Catiolanze* | WW<br>(In-house) | STN10**130**01<br>DE-130A<br>Catioprost | Europe | Approved in November 2023<br>*Plan: FY2024 launch* |
| | | | | Asia | P3 (met primary endpoint) |

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

# Current status of global development (2)

As of January 2024
Updated information is in blue

## Glaucoma and ocular hypertension area

| Indication | Generic Name | Contractual territory | Dev. Code | Development Status | |
|---|---|---|---|---|---|
| Glaucoma | Netarsudil mesilate<br>*Rhopressa®/Rhokiinsa®* | Japan, China<br>Asia, Europe | STN10**139**00<br>AR-13324 | Japan | P3<br>*Plan: FY2024 P3 completion* |
| | | | | Europe | Launched |
| | | | | Asia | Approved<br>*Plan: FY2024 launch* |
| | Netarsudil mesilate /latanoprost (combination)<br>*Rocklatan®/Roclanda®* | Japan, China<br>Asia, Europe | STN10**140**00<br>PG-324 | Europe | Launched |
| | | | | Asia | Approved<br>*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 January 2024
Updated information is in blue

## Keratoconjunctival disease area including dry eye

| Indication | Generic Name | Contractual territory | Dev. Code | Development Status | |
|---|---|---|---|---|---|
| Vernal keratoconjunc-tivitis | Ciclosporin<br>*Verkazia* | WW<br>(In-house) | STN10**076**03[1]<br>DE-076C | China | Approved<br>*Plan: FY2023 launch* |
| Dry eye | Diquafosol sodium (long-lasting)<br>*Diquas LX* | Japan, China<br>Asia, Europe | STN10**089**03<br>DE-089C | Japan | Launched |
| | | | | Asia | Filed<br>*Plan: FY2023 approval* |
| | Olodaterol hydrochloride | WW | STN10**141**00 | Japan | P1/2a<br>*Plan: FY2023 P1/2a completion* |
| Fuchs endothelial corneal dystrophy | Sirolimus (eye drop) | —[2] | STN10**109**04[2] | US<br>France<br>India | P2a<br>*Plan: FY2025 P2a completion* |
| Meibomian gland dysfunction | Sirolimus (eye drop) | WW<br>(In-house) | STN10**109**05 | Japan | P2a (not met primary/secondary endpoints. But observed efficacy on some exploratory endpoints)<br>*Plan: FY2024 start additional P2a* |
| Allergic conjunctivitis | Epinastine HCl (ophthalmic cream) | Japan | STN10**114**02 | Japan | Filed<br>*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 January 2024
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 | P1 *Plan: FY2023 P1 completion* |

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.

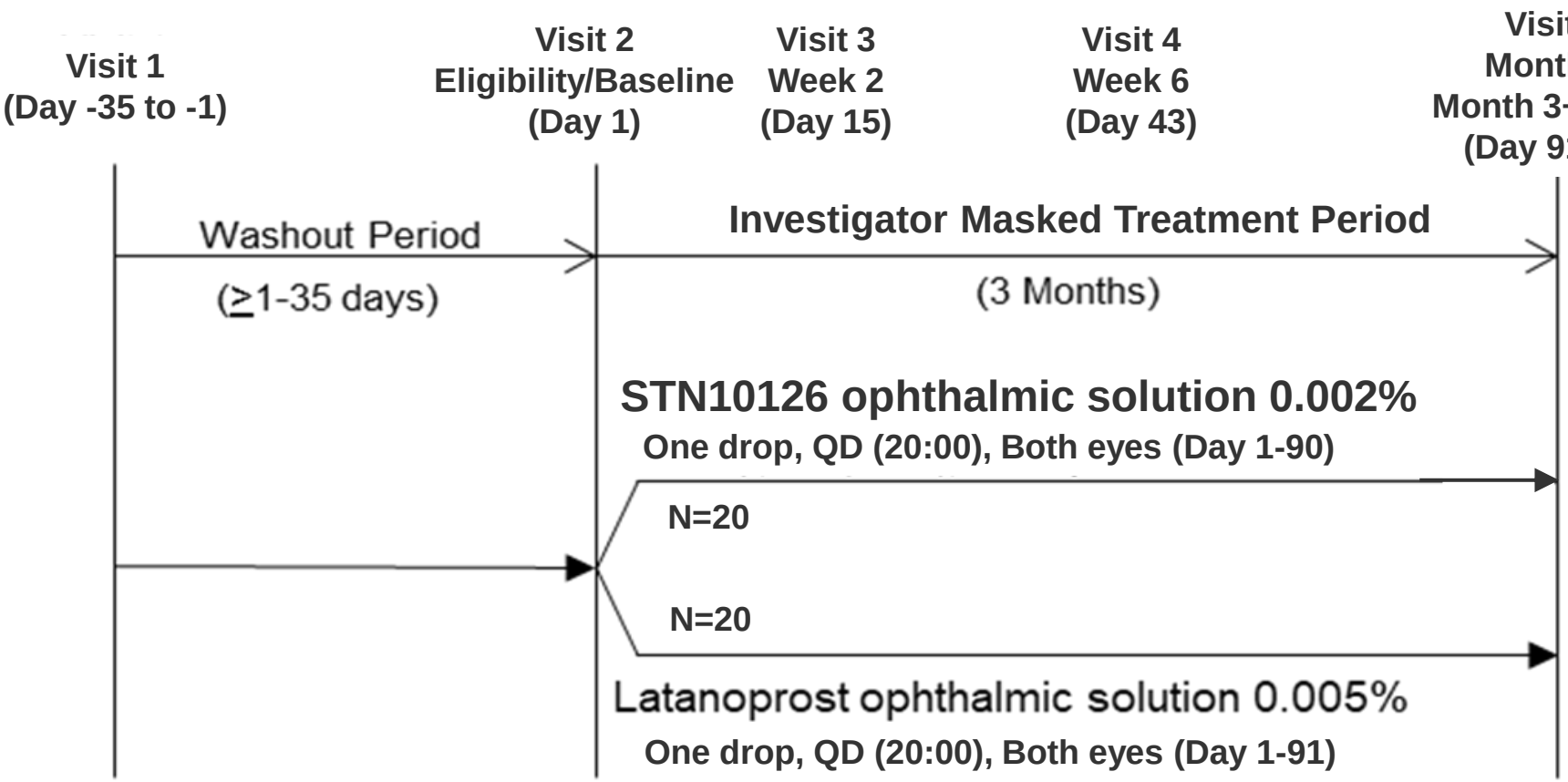
# Current status of global development (5)

As of January 2024
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: FY2024 P3 start* |
| | | | | Asia | *Plan: FY2026 filing* |
| Retinitis pigmentosa | jCell | Japan, China Asia, Europe | STN**6000100** | - | Planning P3 |

# P2 (exploratory study) protocol in Europe



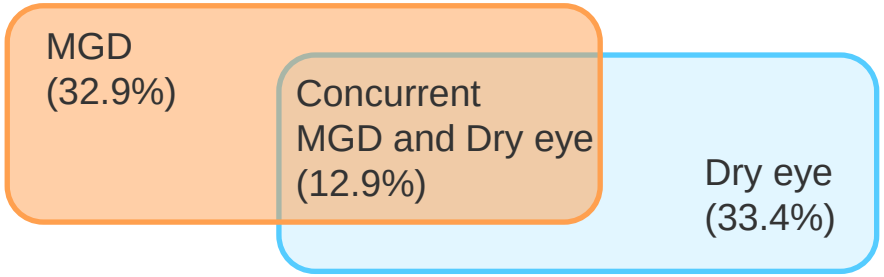

IOP @M3 + 1day

- STN10126: 36/48h after last dosing
- latanoprost: 12/24h after last dosing

# Meibomian Gland Dysfunction (MGD)

- MGD is a condition in which the function of the meibomian glands is diffusely abnormal due to various causes and involves chronic ocular discomfort.
- MGD is highly prevalent, comparable to dry eye (Hirado-Takushima study)

Prevalence




Source: Excerpted from Arita R, et al. *Am J Ophthalmol.* 2019;207:410-418.

- Treatment Options:
  IPL (Intense Pulsed Light), thermal pulsation system, antimicrobial eye drops, warm compress, etc., but currently, no approved eye drops for MGD is available.
- Reference
  Meibomian Gland Dysfunction Clinical Practice Guidelines
  https://link.springer.com/article/10.1007/s10384-023-00995-8

# Forward-looking statements

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