Summary of Consolidated Financial Results for the Nine Months Ended December 31, 2022 (IFRS)

Listed Company Name:	Santen Pharmaceutical Co.,Ltd
Exchanges Listed:	Tokyo (Prime Market)
Stock Code:	4536
URL:	https://www.santen.com/en/
Representative:	Takeshi Ito, President and CEO
Contact:	Guillaume Sakuma, Global Head of IR (+81-6-7664-8621)
Filing of Securities Report (Scheduled):	February 9, 2023
Distribution of Dividends (Scheduled):	—
Preparation of Supplementary Material of the Financial Results:	Yes
Holding of Presentation of Financial Results:	Yes (for securities analysts and institutional investors)

(JPY millions)

1. Consolidated Performance for the Nine Months Ended December 31, 2022

(1) Operating Results

(IFRS)

	Nine months ended December 31, 2021	Nine months ended December 31, 2022	% change
Revenue	195,801	199,786	+2.0%
Operating profit	26,380	(10,147)	—
Profit before tax	25,673	(11,593)	—
Net profit for the period	19,296	(16,088)	—
Net profit for the period attributable to owners of the company	19,349	(16,064)	—
Total comprehensive income for the period	22,803	(6,664)	—
Basic earnings per share (yen)	48.39	(41.13)	
Diluted earnings per share (yen)	48.32	(41.13)	

(Core basis)

	Nine months ended December 31, 2021	Nine months ended December 31, 2022	% change
Revenue	195,801	199,786	+2.0%
Core operating profit	34,553	27,153	(21.4%)
Core net profit for the period	25,865	21,154	(18.2%)
Core net profit for the period attributable to owners of the company	25,907	21,181	(18.2%)
Basic core earnings per share (yen)	64.80	54.19	
Diluted core earnings per share (yen)	64.70	54.11	

(2) Financial Position

	March 31, 2022	December 31, 2022
Total assets	459,976	420,141
Total equity	336,844	300,264
Total equity attributable to owners of the company	337,488	300,927
Total equity attributable to owners of the company ratio	73.4%	71.6%
Equity per share attributable to owners of the company (yen)	843.60	785.28

2. Dividends

	Year to March 2022	Year to March 2023	(Forecasts) Year to March 2023
First quarter dividends per share (yen)	—	—	—
Second quarter dividends per share (yen)	16.00	16.00	—
Third quarter dividends per share (yen)	—	—	—
Year-end dividends per share (yen)	16.00	—	16.00
Annual dividends per share (yen)	32.00	—	32.00

(Note) Revisions to the forecasts of dividends from the latest announcement: No

3. Consolidated Forecasts of Results for the Year Ending March 31, 2023

(IFRS)

	Year to March 2023	% change
Revenue	272,000	+2.2%
Operating profit	(6,500)	—
Profit before tax	(8,500)	—
Net profit for the year	(15,500)	—
Basic earnings per share (yen)	(40.01)	

(Core basis)

	Year to March 2023	% change
Revenue	272,000	+2.2%
Core operating profit	41,000	(11.5%)
Core net profit for the year	30,800	(12.5%)
Basic core earnings per share (yen)	79.50	

(Note) Revisions to the forecasts of consolidated results from the latest announcement: Yes

1. Please refer to "1. Summary of Quarterly Consolidated Results (1) Summary of Consolidated Results" on page 6 of the attached material for details of the reconciliation from IFRS-based figures to core-based figures.
2. At the Board of Directors meeting held on October 4, 2022, the Board resolved to cancel treasury shares and completed the cancellation on October 31, 2022. Subsequently, at a meeting of the Board of Directors on Nov 8, 2022, the Board resolved to undertake a share repurchase. The share cancellation and repurchase have been factored into the basic earnings per share and basic core earnings per share forecasts. Please refer to "2. Condensed Interim Consolidated Financial Statements (5) Notes to Condensed Interim Consolidated Financial Statements on page 17 of the attached material for details.

*Notes

(1) Changes in significant subsidiaries during the period
(Changes in specified subsidiaries resulting in changes in scope of consolidation): No

(2) Changes in accounting policies and accounting estimates

(i) Changes in accounting policies required by IFRS : No
(ii) Changes in accounting policies other than (i) : No
(iii) Changes in accounting estimates : No

(3) Number of ordinary shares issued

(i) Number of shares outstanding at the end of period (including treasury shares)

December 31, 2022	388,219,354 shares
March 31, 2022	400,694,754 shares

(ii) Number of treasury shares at the end of period

December 31, 2022	4,775,109 shares
March 31, 2022	423,668 shares

(iii) Average number of outstanding shares

The Third quarter ended December 31, 2022	390,707,294 shares
The Third quarter ended December 31, 2021	399,708,261 shares

(Note) The number of treasury shares at the end of the period includes shares (16,271 shares at the end of the fiscal year ended March 31, 2022 and 44,551 shares at the end of the third quarter of the fiscal year ending March 31, 2023) owned in trust for the stock compensation system. Treasury shares are also included in the calculation of the average number of shares outstanding during the period.

*This financial summary is not subject to audit by a certified public accountant or auditing firm.

*Explanations and other special notes concerning the appropriate use of business performance forecasts

(Notes on forward-looking statements)
The earnings forecasts and other forward-looking statements contained in this report are based on information currently available to the Company and on certain assumptions deemed to be reasonable by the Company. Actual results may differ from these forecasts due to various factors.

(Method of obtaining supplementary explanatory materials for financial results and results presentation contents)
The Santen Group plans to hold a briefing on the results for securities analysts and institutional investors on February 7, 2023. The materials used in this briefing will be posted on our website.

Accompanying Materials – Contents

1. Summary of Quarterly Consolidated Results

(1) Summary of Consolidated Results
(I) Consolidated Results
A) IFRS

(JPY millions)

	Nine months ended December 31, 2021	Nine months ended December 31, 2022	Year-on-year amount change	Year-on-year change
Revenue	195,801	199,786	3,985	2.0%
Operating profit (loss)	26,380	(10,147)	(36,528)	－%
Net profit (loss) for the period	19,296	(16,088)	(35,384)	－%
Net profit (loss) for the period attributable to owners of the company	19,349	(16,064)	(35,413)	－%

[Revenue]

Revenue in the nine months ended December 31, 2022 increased by 2.0% year-on-year to ¥199.8 billion.

In the mainstay prescription pharmaceuticals business, sales increased by 1.5% year-on-year to ¥185.6 billion partially on FX impact. Despite the strong impact of strict measures in China to prevent the spread of COVID-19 and the following significant rebound after unlocking the measures, the Company was able to minimize the impact of drug price revisions in Japan and posted stable growth in mainstay products in Asia and EMEA.

The breakdown of revenue is as follows:

Upper: Value
Lower: Year-on-year change
【】: Year-on-year change excluding FX impact

(JPY millions)

	Japan	China	Asia	EMEA	Americas	Total
Prescription pharmaceuticals	111,214	16,050	17,080	38,834	2,426	185,604
	(3.9%) 【－%】	(20.9%) 【(31.2%)】	29.5% 【17.6%】	22.8% 【11.6%】	17.4% 【(0.7%)】	1.5% 【(2.7%)】
OTC pharmaceuticals	7,326	195	637	－	－	8,159
	0.6%	－	38.3%	－	－	5.4%
Medical devices	2,452	29	3	1,737	357	4,578
	6.2%	(0.9%)	－	45.2%	12.1%	18.8%
Others	1,304	51	91	－	－	1,446
	8.9%	158.9%	110.5%	－	－	14.7%
Total	122,295	16,325	17,812	40,571	2,783	199,786
	(3.4%) 【－%】	(19.8%) 【(30.1%)】	30.0% 【18.0%】	23.6% 【12.5%】	16.7% 【(1.7%)】	2.0% 【(2.0%)】

(Note)
Represents revenue from sales to external customers.
Classified into countries or regions based on customer location. China is not included in Asia.
EMEA refers to Europe, the Middle East and Africa.

<Prescription pharmaceuticals>

◇ Japan

Revenue in the nine months ended December 31, 2022 decreased by 3.9% year-on-year to ¥111.2 billion. The Company was able to minimize the impact of drug price revisions of mid 4.0% including market expansion re-pricing for mainstay product *Alesion*, through product improvements as in the case of *Diquas LX*, reducing the number of times the eye drops need to be applied to 3 times a day, compared to *Diquas*, and launched in November 2022. Revenue of major products is as follows.

Glaucoma and ocular hypertension		
Tapros ophthalmic solution	¥6.1 billion	(YoY -8.7%)
Tapcom ophthalmic solution	¥2.1 billion	(YoY -3.9%)
Cosopt ophthalmic solution	¥3.7 billion	(YoY -18.3%)
Eybelis ophthalmic solution	¥3.0 billion	(YoY +17.8%)
Dry eye		
Diquas ophthalmic solution *1 (refer to Page 5)	¥12.1 billion	(YoY +17.0%)
Allergy		
Alesion ophthalmic solution *2 (refer to Page 5)	¥12.0 billion	(YoY -16.3%)
Intravitreal VEGF inhibitor		
EYLEA *3 (refer to Page 5) (solution for intravitreal injection)	¥54.7 billion	(YoY -2.2%)

◇ China

On a JPY basis, revenue in the nine months ended December 31, 2022 decreased by 20.9% year-on-year (-31.2% excluding FX impact), to ¥16.1 billion on the impact of strict COVID-19 measures in China and the following significant rebound after removing these measures. Revenue of major products is as follows.

Glaucoma and ocular hypertension		
Tapros ophthalmic solution	¥0.8 billion	(YoY +8.6%)
Dry eye		
Diquas ophthalmic solution	¥2.2 billion	(YoY -16.3%)
Hyalein ophthalmic solution	¥5.0 billion	(YoY -28.7%)
Bacterial conjunctivitis		
Cravit ophthalmic solution	¥4.3 billion	(YoY -22.9%)

◇ Asia (excluding China)

On a JPY basis, revenue in the nine months ended December 31, 2022 increased by 29.5% year-on-year (+17.6% excluding FX impact), to ¥17.1 billion. This was due to promotion efforts of mainstay products. Revenue of major products is as follows.

Glaucoma and ocular hypertension		
Tapros ophthalmic solution	¥1.7 billion	(YoY +10.8%)
Tapcom ophthalmic solution	¥0.8 billion	(YoY +32.9%)
Cosopt ophthalmic solution	¥4.5 billion	(YoY +16.9%)
Dry eye		
Diquas ophthalmic solution	¥1.4 billion	(YoY +9.6%)
Ikervis	¥1.2 billion	(YoY +46.0%)
Bacterial conjunctivitis		
Cravit ophthalmic solution	¥1.8 billion	(YoY +45.0%)

◇ EMEA

On a JPY basis, revenue in the nine months ended December 31, 2022 increased by 22.8% year-on-year (+11.6% excluding FX impact), to ¥38.8 billion, from the mainstay products growth in each of the countries. Revenue of major products is as follows.

Glaucoma and ocular hypertension		
	Tapros ophthalmic solution	¥6.0 billion (YoY +16.0%)
	Tapcom ophthalmic solution	¥3.5 billion (YoY +34.0%)
	Cosopt ophthalmic solution	¥9.9 billion (YoY +23.4%)
	Trusopt ophthalmic solution	¥2.6 billion (YoY +14.6%)
Dry eye		
	Ikervis	¥4.3 billion (YoY +11.5%)
	Cationorm	¥2.1 billion (YoY +31.3%)
Allergy		
	Verkazia	¥0.6 billion (YoY +41.2%)

◇ Americas

On a JPY basis, revenue in the nine months ended December 31, 2022 increased by 17.4% year-on-year (-0.7% excluding FX impact), to ¥2.4 billion.

<OTC pharmaceuticals>

Revenue in the nine months ended December 31, 2022 increased by 5.4% year-on-year to ¥8.2 billion.
Santen continues to focus on high-end products such as the *Sante Medical* series, *Sante Beauteye* series, and *Soft Santear* series as well as *Hyalein S*, which is a switch OTC product and *Sante FX* series and eye drop-type eye wash, *Well-Wash EYE*, which Santen launched in the previous fiscal year.

<Medical devices>

Revenue in the nine months ended December 31, 2022 increased by 18.8% year-on-year to ¥4.6 billion, boosted by the strong performance of *PRESERFLO MicroShunt*. Revenue of major products is as follows.

Lentis Comfort	¥1.0 billion (YoY -5.6%)
PRESERFLO MicroShunt	¥1.7 billion (YoY +45.9%)

<Others>

Other revenues amounted to ¥1.4 billion. This is due to sales of supplements, and cleaning of dustless and aseptic clothing at consolidated subsidiary Claire Co., Ltd.

[Operating loss]

Gross profit in the nine months ended December 31, 2022 increased by 1.1% year-on-year to ¥114.3 billion.
SG&A expenses on an IFRS basis in the nine months ended December 31, 2022 increased by 8.6% year-on-year (+1.0% excluding FX impact) to ¥65.5 billion.
R&D expenses in the nine months ended December 31, 2022 increased by 15.3% year-on-year (+5.1% excluding FX impact) to ¥21.7 billion.

Amortization on intangible assets associated with products in the nine months ended December 31, 2022 decreased by 0.4% year-on-year (-6.3% excluding FX impact) to ¥7.2 billion. This was mainly due to the amortization on intangible assets associated with products acquired from Merck & Co., Inc. (U.S.) in 2014, *Ikervis* which was launched in Europe in 2015, and *PRESERFLO MicroShunt* acquired in connection with the acquisition of InnFocus, Inc. (U.S.) in 2016 and ophthalmic products from Eyevance Pharmaceuticals Holdings Inc. (U.S.) which Santen acquired in 2020. Note that for the amortization on intangible assets associated with eye products related to the acquisition of Eyevance Pharmaceuticals Holdings Inc.(U.S.), given the Company recorded an impairment loss of the whole book value in the second quarter of the fiscal year under review, there has been no addition incurred for the the third quarter of the fiscal year under review.

Other income amounted to ¥0.5 billion.
Other expenses amounted to ¥30.6 billion. This is due to the recording of impairment of the total book value on fixed and intangible assets (goodwill and development and sales rights) associated with Eyevance Pharmaceuticals Holdings Inc.(U.S.) and its business unit Eyevance Pharmaceuticals LLC (U.S.)

As a result, operating loss on an IFRS basis in the nine months ended December 31, 2022 amounted to ¥10.1 billion. (operating profit of ¥26.4 billion for the same period of the previous fiscal year)

[Net loss for the period]

Finance income amounted to ¥1.0 billion.

Finance expenses amounted to ¥0.7 billion.

Share of loss of investments accounted for using equity method amounted to ¥1.7 billion from Twenty Twenty Therapeutics LLC (U.S.), a joint venture with Verily Life Sciences LLC (U.S.)

Income tax expenses decreased by ¥1.9 billion to ¥4.5 billion. This is mainly due to a decrease in profit before tax for the period, associated with the aforementioned decrease of operating profit on an IFRS basis.

As a result, net loss in the period ended December 31, 2022 was ¥16.1 billion (net profit of ¥19.3 billion for the same period of the previous fiscal year)

[Net loss for the period attributable to owners of the parent company]

Quarterly net loss attributable to owners of the company in the nine months ended December 31, 2022 was ¥16.1 billion (Quarterly net profit of ¥19.3 billion for the same period of the previous fiscal year)

*1 Includes *Diquas LX*

*2 Includes *Alesion LX*

*3 Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

B) Core basis*4

(JPY millions)

	Nine months ended December 31, 2021	Nine months ended December 31, 2022	Year-on-year change
Revenue	195,801	199,786	2.0%
Core operating profit	34,553	27,153	(21.4%)
Core net profit for the period	25,865	21,154	(18.2%)
Core net profit for the period attributable to owners of the company	25,907	21,181	(18.2%)

[Revenue]

There are no adjustments from the IFRS basis.

[Core operating profit]

There are no adjustments to gross profit from the IFRS basis.
SG&A expenses in the nine months ended December 31, 2022 increased by 9.6% year-on-year to ¥65.5 billion.
Note that for the third quarter of the previous fiscal year, expenses related to new consolidations associated with business combinations were deducted from IFRS results. However, this adjustment is not applicable to the third quarter under review.
There are no adjustments to R&D expenses from the IFRS basis.

As a result, operating profit on a core basis in the nine months ended December 31, 2022 decreased by 21.4 % year-on-year to ¥27.2 billion.

*4 With the adoption of IFRS in the fiscal year ended March 31, 2015, the Santen Group discloses financial information on a core basis, which is calculated by excluding certain income and expense items from the IFRS basis, as an indicator of profitability from business activities. The core basis is calculated by deducting from IFRS results the following income and expense items as well as related income tax expense adjustments.

- Amortization on intangible assets associated with products
- Other income
- Other expenses
- Finance income
- Finance expenses
- Share of profit (loss) of investments accounted for using equity method
- Expenses related to acquisitions of companies included in SG&A

(II) Research & Development Activities

<Glaucoma and the ocular hypertension area>

STN1011101 (DE-111A, generic name: tafluprost / timolol maleate) is a fixed dose combination drug of a prostaglandin $F_{2\alpha}$ derivative and a beta-adrenergic receptor blocker. The company has conducted Phase 3 trial since January 2019 in China.

STN1011700 (DE-117, generic name: omidenepag isopropyl) is an EP2 receptor agonist. The Company received marketing approval in September 2022 in the U.S. The product was launched in November 2018 in Japan. The Company has successively launched in Asian countries since launch in Korea in February 2021.

STN1012600 (DE-126, generic name: sepetaprost) is a dual agonist that activates both FP and EP3 receptors. An additional Phase 2 trial was completed in December 2021 in the U.S. Phase 3 trials were started in August 2022 in Japan. The Company is conducting a Phase 2 trial (exploratory study) since September 2021 in Europe.

STN2000100 (DE-128) is a device for glaucoma. The Company launched (soft launch) in July 2022 in Japan. The device was launched in April 2019 in Europe. The Company has received approval in Singapore and other countries since September 2021, and launched in Malaysia in October 2022.

STN1013001 (DE-130A, generic name: latanoprost) is an ophthalmic emulsion of a prostaglandin $F_{2\alpha}$ derivative. Phase 3 trial was completed in March 2022 in Asia. The company filed for marketing approval in September 2022 in Europe.

STN1013900 (AR-13324, generic name: netarsudil mesilate) is a ROCK inhibitor. Phase 3 trial has been under way since November 2020 in Japan. Marketing approval has been received in Europe. The Company received marketing approval in January 2023 in Thailand with successive filings planned for other Asian countries.

STN1014000 (PG-324, generic name: netarsudil mesilate / latanoprost) is a fixed dose combination drug of a ROCK inhibitor and a prostaglandin $F_{2\alpha}$ derivative. Marketing approval has been received in Europe and the company launched in January 2023 in Germany. The Company received marketing approval in January 2023 in Thailand with successive filings planned for other Asian countries.

<Keratoconjunctival disease area including dry eye >

STN1007603 (DE-076C, generic name: cyclosporin) for vernal keratoconjunctivitis has been approved and launched in Europe, Asia, and Canada. Marketing approval has been received in April 2022 in China. It was launched in the U.S. in May 2022.

STN1008903 (DE-089C, generic name: diquafosol sodium) is for the treatment of dry eye. The Company launched the product in November 2022 in Japan.

STN1014100 (generic name: olodaterol hydrochloride) is for the treatment of dry eye. Phase 1/2a trial started in January 2023 in Japan.

STN1010905 (generic name: sirolimus) is for the treatment of meibomian gland dysfunction. Phase 2a trial completed in August 2022 in Japan.

STN1011402 (generic name: epinastine hydrochloride) is for the treatment of allergic conjunctivitis. Phase 3 trial completed in October 2022 in Japan.

STN1010904* (generic name: sirolimus) is for the treatment of Fuchs endothelial corneal dystrophy. The Company has executed a joint development agreement with ActualEyes Inc. Phase 2a trials started in U.S., France and India in May 2022. (*The development code (STN1010904) is due to be assigned to the product when Santen obtains an exclusive license upon completion of Phase 2 clinical trial.)

<Refractive error>

STN1012700 (DE-127, generic name: atropine sulfate) is for the treatment of myopia in children. Conducting Phase 2/3 trial since August 2019 in Japan. Phase 2/3 trial was started in June 2022 in China. Phase 2 trial was completed in April 2020 in Asia.

STN1012701 (SYD-101, generic name: atropine sulfate) is for the treatment of progressive myopia in children. Sydnexis Inc., (U.S.) the licensor, is conducting Phase 3 trials in Europe and the U.S. Santen has obtained the exclusive license for

Europe, Middle East and Africa.
STN1013400 (compound name: AFDX0250BS) is for the treatment of myopia. Phase 1 trial was completed in September 2021 in Japan.
STN1013600 (generic name: ursodeoxycholic acid) is for the treatment of presbyopia. Phase 2a trial was started in December 2022 in U.S. Phase 1 trial was completed in April 2022 in Japan.

<Others>

STN1013800 (generic name: oxymetazoline hydrochloride) is for the treatment of ptosis. Phase 3 trial was started in October 2022 in Japan.

※ The numbering method for development codes has changed. Both existing development codes (DE-XXX) and new development codes (STNXXXXXXX) are shown. AR-13324/PG-324 and SYD-101 are the development codes of Alcon, Inc. (U.S.) and Sydnexis Inc. (U.S.) respectively.

(2) Summary of Financial Position

(I) Assets, equity and liabilities

Total assets at the end of the third quarter amounted to ¥420.1 billion, down ¥39.8 billion from the end of the previous fiscal year. Despite an increase in property, plant and equipment related to the construction of the No. 3 plant for the manufacturing of prescription pharmaceutical eye-drops at the Shiga Product Supply Center, there was a decrease in intangible assets associated with the impairment of intangible assets (goodwill and development and sales rights) related to Eyevance Pharmaceuticals Holdings Inc. (U.S.) and Eyevance Pharmaceuticals LLC (U.S.), as well as decreases in trade and other receivables and cash associated with payments including dividends and share repurchases.

Equity amounted to ¥300.3 billion. This was a decrease of ¥36.6 billion from the end of the previous fiscal year ended March 31, 2022, due to share repurchases and a decline in retained earnings resulting from the net loss for the period,despite an increase in other components of equity. The Company completed cancellation of the treasury shares of JPY13bn (12,500,000 shares) on October 31, 2022.

Liabilities amounted to ¥119.9 billion, falling by ¥3.3 billion from the end of the previous fiscal year. This was due to decreases in other financial liabilities related to the repayment of short-term loans, and other current liabilities related to bonus payments, despite an increase in financial liabilities associated with a long-term loan to finance capital expenditures for the construction of the No. 3 plant for the manufacturing of prescription pharmaceutical eye-drops at the Shiga Product Supply Center.

As a result, the ratio of equity attributable to owners of the company to total assets decreased by 1.8 points from the end of the previous fiscal year ended March 31, 2022 to 71.6%

(II) Cash Flows

Cash flows from operating activities at the end of the third quarter amounted to ¥28.5 billion (¥31.2 billion in the nine months ended December 31, 2021). This was mainly due to the ¥16.1 billion quarterly loss, the recording of an impairment loss of ¥30.5 billion mainly from impairment on intangible assets of Eyevance Pharmaceuticals Holdings Inc. (U.S.) and Eyevance Pharmaceuticals LLC (U.S.), ¥13.1 billion in depreciation and amortization, ¥6.1 billion decrease in trade and other receivables and the payment of ¥7.2 billion in corporate tax.

Cash flows from investing activities amounted to an outflow of ¥23.6 billion (¥23.2 billion in the nine months ended December 31, 2021). This was mainly due to payments for the acquisition of property, plant and equipment and intangible assets amounting to ¥14.5 billion and ¥6.2 billion respectively. There was a cash inflow of ¥1.5 billion owing to the sale of 1 equity holding in the third quarter of the fiscal year under review as part of accelerating the ongoing review of cross shareholdings.

Cash flows from financing activities amounted to an outflow of ¥28.0 billion (¥4.1 billion in the nine months ended December 31, 2021). Despite the cash inflow of ¥15.6 billion from long-term loans, the main factors behind the outflow were cash outflows of ¥11.2 billion for short-term loan payments, ¥17.9 billion for share repurchases and ¥12.5 billion for dividends.

As a result, cash and cash equivalents at the end of the third quarter ended December 31, 2022 decreased by ¥21.8 billion from the end of the fiscal year ended March 31, 2022 to ¥61.2 billion.

(III) Information about Forecasts of Consolidated Financial Results and Other Forward-Looking Statements

Given some factors including the slower-than-expected sales progress in China from COVID-19 re-spread and additionally incurred structural reform costs for Americas business, the full-year forecasts for the fiscal year ending March 31, 2023 announced on Nov 8, 2022 have been changed as follows:

(IFRS)

(JPY millions)

	Revenue	Operating profit	Profit before tax	Net profit for the year	Basic earnings per share (yen)
Previous Forecast (A) (Announced on November 8, 2022)	280,000	4,000	3,000	(5,500)	(14.20)
Revised Forecast (B)	272,000	(6,500)	(8,500)	(15,500)	(40.01)
Increase/Decrease (B-A)	(8,000)	(10,500)	(11,500)	(10,000)	
Change	(2.9%)	—	—	—	
(Reference) Consolidated results ended March 31, 2022	266,257	35,886	35,616	27,189	68.07

(Core basis)

(JPY millions)

	Revenue	Core operating profit	Core net profit for the year	Basic core earnings per share (yen)
Previous Forecast (A) (Announced on November 8, 2022)	280,000	45,500	34,100	88.04
Revised Forecast (B)	272,000	41,000	30,800	79.50
Increase/Decrease (B-A)	(8,000)	(4,500)	(3,300)	
Change	(2.9%)	(9.9%)	(9.7%)	
(Reference) Consolidated results ended March 31, 2022	266,257	46,348	35,195	88.16

2. Condensed Interim Consolidated Financial Statements

(1) Condensed Interim Consolidated Statements of Income and Comprehensive Income

IFRS (JPY millions)

	Nine months ended December 31, 2021	Nine months ended December 31, 2022
Revenue	**195,801**	**199,786**
Cost of sales	(82,704)	(85,449)
Gross profit	**113,097**	**114,337**
Selling, general and administrative expenses	(60,323)	(65,502)
Research and development expenses	(18,803)	(21,682)
Amortization on intangible assets associated with products	(7,255)	(7,225)
Other income	318	523
Other expenses	(655)	(30,598)
Operating profit (loss)	**26,380**	**(10,147)**
Finance income	1,212	994
Finance expenses	(734)	(709)
Share of loss of investments accounted for using equity method	(1,186)	(1,731)
Profit (loss) before tax	**25,673**	**(11,593)**
Income tax expenses	(6,377)	(4,495)
Net profit (loss) for the period	**19,296**	**(16,088)**
Other comprehensive income		
Items that will not be reclassified subsequently to profit or loss		
Net gain on financial assets measured at fair value through other comprehensive income	(960)	2,245
Items that may be reclassified subsequently to profit or loss		
Foreign currency translation adjustments	4,183	6,598
Share of other comprehensive income of investments accounted for using equity method	284	581
Other comprehensive income	**3,507**	**9,424**
Total comprehensive income	**22,803**	**(6,664)**
Profit (loss) attributable to		
Owners of the company	19,349	(16,064)
Non-controlling interests	(53)	(24)
Net profit (loss) for the period	**19,296**	**(16,088)**
Total comprehensive income attributable to		
Owners of the company	22,898	(6,646)
Non-controlling interests	(96)	(18)
Total comprehensive income	**22,803**	**(6,664)**
Earnings per share		
Basic earnings (loss) per share (yen)	48.39	(41.13)
Diluted earnings (loss) per share (yen)	48.32	(41.13)

Core basis (JPY millions)

	Nine months ended December 31, 2021	Nine months ended December 31, 2022
Revenue	195,801	199,786
Core operating profit	34,553	27,153
Core net profit for the period	25,865	21,154
Basic core earnings per share (yen)	64.80	54.19
Diluted core earnings per share (yen)	64.70	54.11
Core net profit attributable to		
Owners of the company	25,907	21,181
Non-controlling interests	(42)	(27)
Core net profit for the period	**25,865**	**21,154**

(2) Condensed Interim Consolidated Statements of Financial Position

Assets (JPY millions)

	As of March 31 2022	As of December 31 2022
Non-current assets		
Property, plant and equipment	56,287	65,558
Intangible assets	130,217	100,610
Financial assets	28,673	31,256
Net defined benefit assets	3,011	2,919
Investments from application of equity method	7,565	9,884
Deferred tax assets	3,103	3,032
Other non-current assets	1,695	2,092
Total non-current assets	**230,551**	**215,351**
Current assets		
Inventories	37,141	37,310
Trade and other receivables	99,591	94,201
Other financial assets	1,293	1,098
Income tax receivable	—	1,134
Other current assets	8,387	9,827
Cash and cash equivalents	83,014	61,220
Total current assets	**229,426**	**204,790**
Total assets	**459,976**	**420,141**

Equity and liabilities (JPY millions)

	As of March 31 2022	As of December 31 2022
Equity		
Equity attributable to owners of the company		
Share capital	8,672	8,684
Capital surplus	9,370	9,609
Treasury shares	(718)	(5,264)
Retained earnings	290,477	249,589
Other components of equity	29,688	38,310
Total equity attributable to owners of the company	**337,488**	**300,927**
Non-controlling interests	**(645)**	**(663)**
Total equity	**336,844**	**300,264**
Liabilities		
Non-current liabilities		
Financial liabilities	22,023	37,094
Net defined benefit liabilities	1,077	1,157
Provisions	738	765
Deferred tax liabilities	2,526	4,748
Other non-current liabilities	948	1,173
Total non-current liabilities	**27,312**	**44,936**
Current liabilities		
Trade and other payables	41,185	41,590
Other financial liabilities	38,533	23,874
Income tax payable	4,198	1,315
Provisions	939	1,269
Other current liabilities	10,965	6,893
Total current liabilities	**95,821**	**74,941**
Total liabilities	**123,133**	**119,877**
Total equity and liabilities	**459,976**	**420,141**

(3) Condensed Interim Consolidated Statements of Changes in Equity

Nine months ended December 31, 2021 (JPY millions)

	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity	
					Remeasurements of defined benefit plans	Net gain or loss on financial assets measured at fair value through other comprehensive income
Balance at April 1, 2021	8,525	8,954	(934)	273,238	—	11,075
Comprehensive income						
Net profit (loss) for the period				19,349		
Other comprehensive income						(960)
Total comprehensive income	—	—	—	19,349	—	(960)
Transactions with owners						
Issuance of new shares	18	18				
Acquisition of treasury shares			(12)			
Retirement of treasury shares		15	228			
Dividends				(11,998)		
Share-based payments		81				
Other				508		(508)
Total transactions with owners	18	114	216	(11,489)	—	(508)
Balance at December 31, 2021	8,544	9,068	(718)	281,098	—	9,607

(JPY millions)

	Other components of equity				Total equity attributable to owners of the company	Non-controlling interests	Total equity
	Foreign currency translation adjustments	Share of other comprehensive income of investments accounted for using equity method	Subscription rights to shares	Total			
Balance at April 1, 2021	8,634	170	518	20,398	310,181	(535)	309,646
Comprehensive income							
Net profit (loss) for the period				—	19,349	(53)	19,296
Other comprehensive income	4,225	284		3,549	3,549	(43)	3,507
Total comprehensive income	4,225	284	—	3,549	22,898	(96)	22,803
Transactions with owners							
Issuance of new shares			(24)	(24)	12		12
Acquisition of treasury shares				—	(12)		(12)
Retirement of treasury shares				—	243		243
Dividends				—	(11,998)		(11,998)
Share-based payments				—	81		81
Other				(508)	—		—
Total transactions with owners	—	—	(24)	(533)	(11,674)	—	(11,674)
Balance at December 31, 2021	12,859	454	494	23,415	321,405	(630)	320,775

Nine months ended December 31, 2022 (JPY millions)

	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity	
					Remeasurements of defined benefit plans	Net gain or loss on financial assets measured at fair value through other comprehensive income
Balance at April 1, 2022	8,672	9,370	(718)	290,477	—	8,438
Comprehensive income						
Net profit (loss) for the period				(16,064)		
Other comprehensive income						2,245
Total comprehensive income	—	—	—	(16,064)	—	2,245
Transactions with owners						
Issuance of new shares	12	12				
Acquisition of treasury shares		(30)	(17,907)			
Retirement of treasury shares		(2)	364			
Cancellation of treasury shares		(12,998)	12,998			
Transfer to Retained earnings from Capital surplus		12,993		(12,993)		
Dividends				(12,611)		
Share-based payments		263				
Other				780		(780)
Total transactions with owners	12	239	(4,546)	(24,824)	—	(780)
Balance at December 31, 2022	8,684	9,609	(5,264)	249,589	—	9,903

(JPY millions)

	Other components of equity				Total equity attributable to owners of the company	Non-controlling interests	Total equity
	Foreign currency translation adjustments	Share of other comprehensive income of investments accounted for using equity method	Subscription rights to shares	Total			
Balance at April 1, 2022	19,950	914	384	29,688	337,488	(645)	336,844
Comprehensive income							
Net profit (loss) for the period				—	(16,064)	(24)	(16,088)
Other comprehensive income	6,593	581		9,418	9,418	6	9,424
Total comprehensive income	6,593	581	—	9,418	(6,646)	(18)	(6,664)
Transactions with owners							
Issuance of new shares			(16)	(16)	7		7
Acquisition of treasury shares				—	(17,937)		(17,937)
Retirement of treasury shares				—	362		362
Cancellation of treasury shares				—	—		—
Transfer to Retained earnings from Capital surplus				—	—		—
Dividends				—	(12,611)		(12,611)
Share-based payments				—	263		263
Other				(780)	—		—
Total transactions with owners	—	—	(16)	(797)	(29,916)	—	(29,916)
Balance at December 31, 2022	26,543	1,495	368	38,310	300,927	(663)	300,264

(4) Condensed Interim Consolidated Statements of Cash Flows

(JPY millions)

	Nine months ended December 31, 2021	Nine months ended December 31, 2022
I. Cash flows from operating activities:		
Net profit (loss) for the period	19,296	(16,088)
Depreciation and amortization	12,543	13,145
Impairment losses	64	30,512
Shares of loss (profit) of entities accounted for using equity method	1,186	1,731
Finance expenses (income)	(607)	(436)
Income tax expenses	6,377	4,495
Decrease (increase) in trade and other receivables	3,246	6,124
Decrease (increase) in inventories	2,568	611
Increase (decrease) in trade and other payables	(20)	261
Increase (decrease) in provisions and net defined benefit liabilities	264	348
Decrease (increase) in other current assets	(2,515)	(981)
Increase (decrease) in accounts payable - bonuses	(2,549)	(3,147)
Increase (decrease) in accounts payable-other	(778)	(2,290)
Other	1,451	1,032
Subtotal	40,525	35,317
Interest received	222	199
Dividends received	493	461
Interest paid	(156)	(305)
Income tax paid	(9,896)	(7,193)
Net cash flows from (used in) operating activities	**31,188**	**28,480**
II. Cash flows from investing activities:		
Payments for acquisition of investments	(823)	(586)
Proceeds from sales of investments	1,098	1,489
Payments for acquisition of property, plant and equipment	(14,921)	(14,452)
Payments for acquisition of intangible assets	(5,592)	(6,208)
Payments for acquisition of investments accounted for using equity method	(2,969)	(3,470)
Other	(30)	(372)
Net cash flows from (used in) investing activities	**(23,237)**	**(23,600)**
III. Cash flows from financing activities:		
Repayments of short-term loans	—	(11,234)
Proceeds from long-term loans	10,000	15,617
Purchase of treasury shares	(12)	(17,907)
Dividends paid	(11,911)	(12,506)
Repayments of lease obligation	(2,236)	(2,602)
Other	12	639
Net cash flows from (used in) financing activities	**(4,148)**	**(27,994)**
IV. Net increase (decrease) in cash and cash equivalents	**3,804**	**(23,114)**
V. Cash and cash equivalents at the beginning of period	**62,888**	**83,014**
VI. Effect of exchange rate changes on cash and cash equivalents	**1,140**	**1,320**
VII. Cash and cash equivalents at the end of period	**67,833**	**61,220**

(5) Notes to Condensed Interim Consolidated Financial Statements

(Going Concern Assumption)

Not applicable.

(Other expenses)

Nine months ended December 31, 2022

The Company recorded an impairment loss of ¥30,512 million included in other expenses of the Condensed Interim Consolidated Statements of Income and Comprehensive Income.

This is mainly due to the recognition of impairment loss in the second quarter of the fiscal year under review of ¥30,008 million related to intangible assets associated with products, goodwill and property, plant and equipment of Eyevance Pharmaceuticals Holdings Inc.(U.S.) and Eyevance Pharmaceuticals LLC (U.S.), where the Company reduced related book value to the recoverable amount.

(¥22,296 million of intangible assets associated with products, ¥7,418 million of goodwill, ¥294 million of property, plant and equipment)

(Statement of Significant Changes in Shareholders' Equity)

Nine months ended December 31, 2022

(Repurchase of own shares)

At a meeting of the Board of Directors on May 10, 2022, the Board resolved to repurchase its own shares in accordance with Article 156 of the Companies Act (Japan), as applied pursuant to Article 165, paragraph 3.

Santen repurchased a total of 12,500,000 of its own shares for a total value of 12,733 million yen during the period between May 11, 2022 to September 30, 2022. Santen completed the share buyback based on the resolution above on September 8, 2022 (execution date basis).

Subsequently, at a meeting of the Board of Directors on November 8, 2022, the Board resolved to repurchase its own shares in accordance with Article 156 of the Companies Act (Japan), as applied pursuant to Article 165, paragraph 3. Accordingly, the Company repurchased a total of 4,427,600 of its own shares for a total value of 4,900 million yen during the period between November 9, 2022 to December 31, 2022.

(I) Reasons for repurchase of own shares

To enhance capital efficiency and improve return of profits.

(II) Details of repurchase

(1) Class of shares to be acquired	Common shares
(2) Total number of shares to be acquired	13,000,000 shares (maximum) *Representing 3.4% of the total number of shares outstanding (excluding treasury shares)
(3) Total amount of acquisition	13.0 billion yen (maximum)
(4) Period of acquisition	November 9, 2022 to March 24, 2023
(5) Method of acquisition	Open-market repurchase by the discretionary trading method
(6) Other	After repurchase, Santen plans to cancel the repurchased shares by the resolution of its Board of Directors in accordance with Article 178 of the Companies Act (Japan).

(Cancellation of treasury shares)

The Company resolved at the Board of Directors meeting held on October 4, 2022 to cancel treasury shares as stated below, in accordance with Article 178 of the Companies Act (Japan) . The treasury shares were cancelled on October 31, 2022.

The treasury shares cancelled as stated below were treasury shares that were acquired in accordance with the Board resolution of May 10, 2022 to repurchase shares.

(1) Class of shares to be canceled	Common shares
(2) Total number of shares to be canceled	12,500,000 shares (The ratio against total number of the outstanding shares before the Cancellation: 3.1%)
(3) Date of cancellation	October 31, 2022

(Significant Subsequent Events)

Implementation of structural reform in Americas

At a meeting of the Board of Directors on February 7, 2023, the Board resolved to undergo structural reforms to streamline the pharmaceutical commercial business in Americas to the fullest extent with the aim of improving profitability. Related to the implementation of structural reform for Americas business, the Company currently estimates approximately ¥6.5 billion to be incurred and categorized into other expenses under the fourth quarter of the fiscal year under review.

3. Consolidated Reference

(1) Revenue of Major Products

(JPY millions)

Brand Name	Region	Year ended March 31, 2022				Year ending March 31, 2023			
		Nine months ended December 31, 2021 Actual	Changes from the same period of previous year	Year ended March 31, 2022 Actual	Changes from the same period of previous year	Nine months ended December 31, 2022 Actual	Changes from the same period of previous year	Forecast for the fiscal year ending March 31, 2023	Changes from the same period of the previous year
Glaucoma and ocular hypertension									
Cosopt	Total	16,397	1.5%	21,752	4.2%	18,093	10.3%	22,225	2.2%
	Japan	4,542	(19.9%)	5,650	(18.6%)	3,709	(18.3%)	4,677	(17.2%)
	Asia	3,810	17.0%	5,157	15.6%	4,452	16.9%	5,796	12.4%
	EMEA	8,046	11.3%	10,945	15.5%	9,931	23.4%	11,752	7.4%
Tapros	Total	14,046	0.9%	18,423	2.8%	14,519	3.4%	18,169	(1.4%)
	Japan	6,655	(5.2%)	8,409	(3.4%)	6,075	(8.7%)	7,673	(8.8%)
	China	723	86.7%	1,170	94.3%	785	8.6%	902	(23.0%)
	Asia	1,501	5.5%	2,077	8.9%	1,663	10.8%	2,325	12.0%
	EMEA	5,168	1.5%	6,767	1.1%	5,996	16.0%	7,269	7.4%
Tapcom	Total	5,344	15.1%	6,971	15.5%	6,337	18.6%	8,201	17.7%
	Japan	2,156	4.4%	2,738	5.1%	2,071	(3.9%)	2,629	(4.0%)
	Asia	584	49.3%	815	49.3%	777	32.9%	1,090	33.7%
	EMEA	2,604	19.1%	3,417	18.4%	3,489	34.0%	4,483	31.2%
Trusopt	Total	3,423	(0.2%)	4,374	0.2%	3,685	7.7%	4,476	2.3%
	Japan	888	(11.3%)	1,108	(9.7%)	778	(12.3%)	973	(12.2%)
	Asia	278	7.8%	382	10.9%	320	14.9%	390	2.1%
	EMEA	2,257	4.0%	2,883	3.2%	2,587	14.6%	3,112	7.9%
Eybelis	Total	2,617	34.7%	3,420	34.8%	3,171	21.2%	4,181	22.3%
	Japan	2,541	30.8%	3,304	31.3%	2,994	17.8%	3,836	16.1%
	Asia	76	—	116	475.4%	177	134.4%	289	150.1%
Dry eye									
Diquas (Including Diquas LX)	Total	14,249	28.2%	18,835	30.8%	15,701	10.2%	22,793	21.0%
	Japan	10,313	7.2%	13,342	8.6%	12,070	17.0%	18,009	35.0%
	China	2,639	544.0%	4,074	468.5%	2,209	(16.3%)	2,760	(32.3%)
	Asia	1,298	20.0%	1,419	1.1%	1,422	9.6%	2,024	42.6%
Hyalein	Total	13,247	(10.1%)	17,779	(3.5%)	11,633	(12.2%)	13,822	(22.3%)
	Japan	5,119	(8.2%)	6,466	(7.2%)	4,485	(12.4%)	5,078	(21.5%)
	China	6,950	(3.5%)	8,943	(3.4%)	4,956	(28.7%)	6,463	(27.7%)
	Asia	1,178	(39.6%)	2,370	8.0%	2,192	86.1%	2,282	(3.7%)
Ikervis	Total	4,652	39.4%	5,856	29.3%	5,469	17.6%	7,158	22.2%
	Asia	812	25.5%	1,106	24.2%	1,186	46.0%	1,465	32.4%
	EMEA	3,840	42.8%	4,750	30.6%	4,283	11.5%	5,693	19.9%
Cationorm	Total	2,537	7.2%	3,230	5.5%	3,288	29.6%	4,183	29.5%
	Asia	358	80.0%	467	82.5%	341	(4.8%)	440	(5.7%)
	EMEA	1,631	9.2%	2,078	5.6%	2,141	31.3%	2,564	23.4%
	Americas	548	(18.6%)	685	(18.3%)	806	47.2%	1,179	72.2%
Allergy									
Alesion (Including Alesion LX)	Total	14,467	14.2%	29,392	(10.3%)	12,155	(16.0%)	28,840	(1.9%)
	Japan	14,385	13.5%	29,286	(10.5%)	12,040	(16.3%)	28,660	(2.1%)
	Asia	81	—	106	465.8%	115	41.3%	180	69.3%
Verkazia	Total	464	295.7%	633	255.2%	771	66.0%	1,100	73.6%
	EMEA	425	303.8%	585	260.6%	600	41.2%	806	37.8%
	Americas	39	224.8%	49	201.0%	170	335.4%	238	389.2%
Intravitreal VEGF inhibitor									
EYLEA	Total	55,926	9.8%	72,484	12.5%	54,722	(2.2%)	67,237	(7.2%)
	Japan	55,926	9.8%	72,484	12.5%	54,722	(2.2%)	67,237	(7.2%)
Bacterial conjunctivitis									
Cravit	Total	9,142	(12.5%)	11,712	(7.4%)	8,214	(10.1%)	10,670	(8.9%)
	Japan	1,440	(10.4%)	1,754	(11.0%)	1,022	(29.1%)	1,360	(22.5%)
	China	5,559	(15.9%)	6,966	(12.1%)	4,289	(22.9%)	5,816	(16.5%)
	Asia	1,229	(12.9%)	1,866	8.3%	1,782	45.0%	2,210	18.5%
	EMEA	914	10.6%	1,126	9.4%	1,122	22.8%	1,284	14.1%
Medical devices									
Lentis comfort	Total	1,059	27.8%	1,422	18.9%	999	(5.6%)	1,547	8.8%
	Japan	1,059	27.8%	1,422	18.9%	999	(5.6%)	1,547	8.8%
PRESERFLO MicroShunt	Total	1,167	85.6%	1,612	80.9%	1,734	45.9%	2,385	47.9%
	EMEA	1,167	85.6%	1,612	80.9%	1,707	46.2%	2,363	46.6%
OTC Pharmaceuticals	Total	7,742	4.8%	9,780	3.9%	8,159	5.4%	10,347	5.8%
	Japan	7,281	2.1%	9,185	1.4%	7,326	0.6%	9,331	1.6%
	China	—	—	7	—	195	—	288	—
	Asia	461	80.1%	588	67.1%	637	38.3%	728	23.9%

(2) FOREX

(JPY)

Exchange rate (yen)	Major currency	3rd quarter ended December 31, 2021	Fiscal year ended March 31, 2022	3rd quarter ended December 31, 2022	Fiscal year ending March 31, 2023 (Forecasts)
	USD	111.24	112.57	136.22	140.00
	EUR	130.80	130.75	140.43	140.00
	CNY	17.28	17.55	19.86	20.00

Forecasts in this reports are based on the currently available information. Actual results may differ materially depending on a number of factors including changes to the business environment and others. Our full-year forecasts are based on our foreign exchange assumptions. Revenue by region shows that of major countries or regions.

(3) Research & Development

As of January 2023

Pipeline Development Status (Clinical Stage)

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
cyclosporin	STN1007603 / DE-076C	Vernal keratoconjunctivitis	Original	U.S.					May-2022	
				China					Apr-2022	

An ophthalmic emulsion which improves vernal keratoconjunctivitis by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue penetration. Launched successively in European countries since October 2018. Launched successively in Asian countries after receiving approval for an indication expansion for Ikervis in August 2019. Launched in November 2019 in Canada. Launched in May 2022 in the U.S. and received marketing approval in April 2022 in China.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
diquafosol sodium	STN1008903 / DE-089C	Dry eye	Merck Sharp & Dohme Corp. (U.S.)	Japan						Nov-2022

A dry eye treatment which stimulates secretion of mucin and aqueous components from the corneal and conjunctival epithelium. Long-acting drug. Launched in November 2022 in Japan.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
sirolimus	STN1010904	Fuchs endothelial corneal dystrophy	Joint development with ActualEyes	U.S. France India	(Phase 2a)					

An ophthalmic suspension which treats Fuchs endothelial corneal dystrophy via mTOR inhibition. Started Phase 2a in U.S., France and India in May 2022. (*The development code (STN1010904) is due to be assigned to the product when Santen obtains an exclusive license upon completion of Phase 2 clinical trial)

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
sirolimus	STN1010905	Meibomian gland dysfunction	Original	Japan	(Phase 2a)					

An ophthalmic suspension which improves meibomian gland function via mTOR inhibition. Completed Phase 2a in August 2022 in Japan.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
tafluprost/ timolol maleate	STN1011101 /DE-111A	Glaucoma/ Ocular hypertension	Co-development with AGC	China						

A fixed dose combination drug of a prostaglandin $F_{2\alpha}$ derivative and a beta-adrenergic receptor blocker. Launched in Japan in November 2014. Launched successively in European countries since January 2015. Launched successively in Asian countries since April 2016. Started Phase 3 in January 2019 in China.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
epinastine hydrochloride	STN1011402	Allergic conjunctivitis	Nippon Boehringer Ingelheim	Japan						

A histamine H_1 receptor antagonist with mediator release inhibitor function, as treatment for allergic conjunctivitis. Ophthalmic cream. Completed Phase 3 in October 2022 in Japan.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
omidenepag isopropyl	STN1011700 /DE-117	Glaucoma/ Ocular hypertension	Co-development with UBE Corporation	U.S.					Sep-2022	
				Japan						Nov-2018
				Asia						Feb-2021

An EP2 receptor agonist with a new mechanism of action. Received marketing approval in September 2022 in the U.S.. Launched in November 2018 in Japan. Launched successively in Asian countries since launch in February 2021 in Korea.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
sepetaprost	STN1012600 / DE-126	Glaucoma/ Ocular hypertension	ONO PHARMACEUTICAL	U.S.						
				Japan						
				Europe	(Exploratory study)					

A prostaglandin analogue eye drop drug product with a novel mode of action that is a dual agonist for both FP and EP3 receptors for the treatment of glaucoma and ocular hypertension. Completed an additional Phase 2 in December 2021 in the U.S.. Started Phase 3 in August 2022 in Japan. Conducting Phase 2 (exploratory study) since September 2021 in Europe.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
atropine sulfate	STN1012700 / DE-127	Myopia	Singapore Health Services, Nanyang Technological University	Japan			(Phase 2/3)			
				China			(Phase 2/3)			
				Asia						

Non-selective muscarinic antagonist which reduces progression of juvenile myopia. Conducting Phase 2/3 from August 2019 in Japan. Started Phase 2/3 in June 2022 in China. Completed Phase 2 in April 2020 in Asia.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
atropine sulfate	STN1012701 / SYD-101	Myopia	Sydnexis Inc.	Europe						

Non-selective muscarinic antagonist which reduces progression of juvenile myopia. Sydnexis Inc., the licensor, is conducting Phase 3 trial in Europe and the U.S. Santen has obtained the exclusive license for Europe, Middle East and Africa.

—	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
glaucoma implant device	STN2000100 / DE-128	Glaucoma	Original	Japan						Jul-2022
				Europe						Apr-2019
				Asia						Oct-2022
A drainage implant device designed to lower intraocular pressure (IOP) for the treatment of primary open-angle glaucoma through the drainage of aqueous humor. Launched (soft launch) in July 2022 in Japan. Launched in Europe in April 2019. In Asia received approval in Singapore and other countries since September 2021, and launched in October 2022 in Malaysia.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
latanoprost	STN1013001 /DE-130A (Catioprost)	Glaucoma/ Ocular hypertension	Original	Europe				Sep-2022		
				Asia						
An ophthalmic emulsion of a prostaglandin $F_2\alpha$ derivative, for the treatment of glaucoma and ocular hypertension. Completed Phase 3 in March 2022 in Europe and Asia. Filed for marketing approval in September 2022 in Europe.										

Compound name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
AFDX0250BS	STN1013400	Myopia	Boehringer Ingelheim	Japan						
Selective muscarinic M2 antagonist which reduces progression of juvenile myopia. Reduce mydriasis by selectively inhibiting a subtype of receptors. Completed Phase1 in September 2021 in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
ursodeoxycholic acid	STN1013600	Presbyopia	Original	U.S.		(Phase 2a)				
				Japan						
Improvement of presbyopia by improving lens elasticity. Started P2a in December 2022 in U.S.. Completed Phase 1 in April 2022 in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
oxymetazoline hydrochloride	STN1013800	Ptosis	RVL Pharmaceuticals	Japan						
A direct-acting alpha adrenergic receptor agonist. Developed and sold by RVL Pharmaceuticals in the U.S.. Started Phase 3 in October 2022 in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
netarsudil mesilate	STN1013900 / AR-13324	Glaucoma / Ocular hypertension	Alcon*	Japan						
				Europe						
				Asia				Jan-2023		
A ROCK (Rho-associated kinase) inhibitor. Developed and sold by Alcon in the U.S.. Conducting Phase 3 from November 2020 in Japan. Received marketing approval in Europe. Received marketing approval in January 2023 in Thailand with successive filings made in Asian countries.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
netarsudil mesilate / latanoprost	STN1014000 / PG-324	Glaucoma / Ocular hypertension	Alcon*	Europe						Jan-2023
				Asia					Jan-2023	
A fixed dose combination drug of a ROCK (Rho-associated kinase) inhibitor and a prostaglandin $F_2\alpha$ derivative. Developed and sold by Alcon in the U.S. Received marketing approval in Europe and launched in January 2023 in Germany. Received marketing approval in January 2023 in Thailand with successive filings planned for Asian countries.										

*changed to Alcon due to the completion of its acquisition of Aerie Pharmaceuticals, Inc. in Nov 2022

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
olodaterol hydrochloride	STN1014100	Dry eye	Boehringer Ingelheim	Japan		(Phase 1/2a)				
β2 receptor agonist. Started Phase 1/2a in January 2023 in Japan.										

Changes from Q2 FY2022 (November 8, 2022)

Dev. Code	Changes
STN1008903 / DE-089C	Launched in November 2022 in Japan.
STN2000100 / DE-128	Launched in October 2022 in Malaysia.
STN1013600	Started P2a in December 2022 in U.S.
STN1013900 / AR-13324	Received marketing approval in January 2023 in Thailand.
STN1014000 / PG-324	Launched in January 2023 in Germany. Received marketing approval in January 2023 in Thailand.
STN1014100	Started Phase 1/2a in January 2023 in Japan.

(3) Capital Expenditures, Depreciation and Amortization, Amortization on Intangible Assets Related to Products, and Research and Development Expenses

Capital expenditures (JPY millions)

	Nine months ended December 31, 2021	Year ended March 31, 2022	Nine months ended December 31, 2022	Year ending March 31, 2023
	Actual			Forecast
Consolidated	16,216	22,244	17,295	25,000

(Note) Excluding the increase in right-of-use assets.

Depreciation and amortization (JPY millions)

	Nine months ended December 31, 2021	Year ended March 31, 2022	Nine months ended December 31, 2022	Year ending March 31, 2023
	Actual			Forecast
Manufacturing cost	1,716	2,309	1,743	2,400
Selling, general and administrative expenses	1,198	1,654	1,603	2,300
R&D expenses	434	577	456	780
Consolidated total	3,348	4,540	3,802	5,480

(Note) Excluding amortization on intangible assets associated with products, long-term advance expense and right-of-use assets.

Amortization on intangible assets associated with products (JPY millions)

	Nine months ended December 31, 2021	Year ended March 31, 2022	Nine months ended December 31, 2022	Year ending March 31, 2023
	Actual			Forecast
Intangible assets (Merck products)	4,305	5,740	4,356	5,740
Intangible assets (Eyevance)	1,407	1,899	1,149	1,180
Intangible assets (PRESERFLO MicroShunt))	708	955	867	1,190
Intangible assets (Ikervis)	556	741	597	790
Other	278	398	257	430
Consolidated total	7,255	9,734	7,225	9,330

Research and development expenses (JPY millions)

	Nine months ended December 31, 2021	Year ended March 31, 2022	Nine months ended December 31, 2022	Year ending March 31, 2023
	Actual			Forecast
Consolidated	18,803	26,377	21,682	29,500
Percent of revenue	9.6%	9.9%	10.9%	10.8%

Forecasts in this report are based on the currently available information. Actual results may differ materially depending on a number of factors including adverse economic conditions and others.