Summary of Consolidated Financial Results for the Six Months Ended September 30, 2021 (IFRS)

Listed Company Name:	Santen Pharmaceutical Co.,Ltd
Exchanges Listed:	Tokyo (First section)
Stock Code:	4536
URL:	https://www.santen.com
Representative:	Shigeo Taniuchi, President and CEO
Contact:	Kaori Itagaki, IR Group Manager (+81-6-7664-8621)
Filing of Securities Report (Scheduled):	November 10, 2021
Distribution of Dividends (Scheduled):	November 30, 2021
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 Six Months Ended September 30, 2021

(1) Operating Results

(IFRS)

	Six months ended September 30, 2020	Six months ended September 30, 2021	% change
Revenue	118,905	128,759	+8.3%
Operating profit	18,686	18,805	+0.6%
Profit before tax	18,353	18,393	+0.2%
Net profit for the period	13,698	14,254	+4.1%
Net profit for the period attributable to owners of the company	13,813	14,307	+3.6%
Total comprehensive income for the period	18,498	14,858	(19.7%)
Basic earnings per share (yen)	34.58	35.79	
Diluted earnings per share (yen)	34.50	35.73	

(Core basis)

	Six months ended September 30, 2020	Six months ended September 30, 2021	% change
Revenue	118,905	128,759	+8.3%
Core operating profit	25,690	24,306	(5.4%)
Core net profit for the period	19,687	18,556	(5.7%)
Core net profit for the period attributable to owners of the company	19,703	18,586	(5.7%)
Basic core earnings per share (yen)	49.33	46.50	
Diluted core earnings per share (yen)	49.21	46.41	

(2) Financial Position

	March 31, 2021	September 30, 2021
Total assets	405,285	420,435
Total equity	309,646	319,029
Total equity attributable to owners of the company	310,181	319,632
Total equity attributable to owners of the company ratio	76.5%	76.0%
Equity per share attributable to owners of the company (yen)	776.16	799.56

(Note) With regard to provisional accounting treatment related to a business combination in September 2020, in conjunction with the completion of purchase price adjustments in the second quarter of the fiscal year ending March 2022, the consolidated earnings and financial position for the second quarter of the fiscal year ended March 2021 has been retroactively restated.

2. Dividends

	Year to March 2021	Year to March 2022	(Forecasts) Year to March 2022
First quarter dividends per share (yen)	—	—	—
Second quarter dividends per share (yen)	14.00	16.00	—
Third quarter dividends per share (yen)	—	—	—
Year-end dividends per share (yen)	14.00	—	16.00
Annual dividends per share (yen)	28.00	—	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, 2022

(IFRS)

	Year to March 2022	% change
Revenue	260,000	+4.2%
Operating profit	41,500	+240.5%
Profit before tax	41,000	+250.8%
Net profit for the year	30,500	+234.2%
Basic earnings per share (yen)	77.07	

(Core basis)

	Year to March 2022	% change
Revenue	260,000	+4.2%
Core operating profit	52,000	+3.8%
Core net profit for the year	39,000	+3.9%
Basic core earnings per share (yen)	98.34	

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

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 basis figures to core-based figures.

*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)

September 30, 2021	400,400,954 shares
March 31, 2021	400,368,954 shares

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

September 30, 2021	423,603 shares
March 31, 2021	549,909 shares

(iii) Average number of outstanding shares

The Second quarter ended September 30, 2021	399,679,863 shares
The Second quarter ended September 30, 2020	399,394,844 shares

(Note)The number of treasury shares at the end of the period includes shares owned in trust for the stock compensation system(18,230 shares at the end of the fiscal year ended March 31, 2021 and 16,271 shares as of the second quarter of the fiscal year ending March 31, 2022). 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 November 9, 2021. 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)

	Six months ended September 30, 2020	Six months ended September 30, 2021	Year-on-year change
Revenue	118,905	128,759	8.3%
Operating profit	18,686	18,805	0.6%
Net profit for the period	13,698	14,254	4.1%
Net profit for the period attributable to owners of the company	13,813	14,307	3.6%

[Revenue]

Revenue in the six months ended September 30, 2021 increased by 8.3% year-on-year to ¥128.8 billion.
In the mainstay prescription pharmaceuticals business, sales grew by 8.0% year-on-year to ¥120.4 billion. This is due to the steady growth in mainstay products despite the impact of drug price revisions in Japan, the minimization of the impact of volume-based purchasing in China, as well as the stable growth in mainstay products in 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	75,675	13,998	8,728	20,501	1,469	120,370
	6.4%	10.0%	(2.9%)	13.6%	155.6%	8.0%
	【－%】	【(1.9%)】	【(9.5%)】	【5.3%】	【147.9%】	【4.7%】
OTC pharmaceuticals	4,791	－	296	－	－	5,087
	(0.7%)	－	67.1%	－	－	1.7%
Medical devices	1,542	－	－	742	198	2,481
	15.4%	(100.0%)	－	95.2%	－	44.5%
Others	770	17	33	－	－	820
	21.2%	(38.4%)	(5.5%)	－	－	17.5%
Total	82,777	14,015	9,057	21,242	1,667	128,759
	6.2%	9.9%	(1.5%)	15.3%	190.1%	8.3%

(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 six months ended September 30, 2021 increased by 6.4% year-on-year to ¥75.7 billion.
Revenue of major products are as follows.

Glaucoma and ocular hypertension		
Tapros ophthalmic solution	¥4.4 billion	(YoY -4.5%)
Tapcom ophthalmic solution	¥1.4billion	(YoY +5.7%)
Eybelis ophthalmic solution	¥1.6 billion	(YoY +34.8%)
Dry Eye		
Diquas ophthalmic solution	¥6.7 billion	(YoY +9.4%)
Allergy		
Alesion ophthalmic solution *1(refer to Page5)	¥9.5 billion	(YoY +23.5%)
Intravitreal VEGF inhibitor		
EYLEA *2(refer to Page5) (solution for intravitreal injection)	¥36.5 billion	(YoY +9.6%)

◇ China

On a JPY basis, revenue in the six months ended September 30, 2021 increased by 10.0% year-on-year (-1.9% excluding FX impact), to ¥14.0 billion. The Company has focused further on strengthening sales promotion of *Diquas* and *Tapros* ophthalmic solution which are new products in China as well as expanding other market channels such as private hospitals and pharmacies although revenue from mainstay products' *Cravit* and *Hyalein* ophthalmic solution was impacted by volume-based purchasing. Revenue of major products are as follows.

Glaucoma and ocular hypertension		
Tapros ophthalmic solution	¥0.5 billion	(YoY +101.9%)
Dry Eye		
Diquas ophthalmic solution	¥1.7 billion	(YoY +591.4%)
Hyalein ophthalmic solution	¥4.2 billion	(YoY -11.6%)
Bacterial conjunctivitis		
Cravit ophthalmic solution	¥4.4 billion	(YoY -10.7%)

◇ Asia (excluding China)

On a JPY basis, revenue in the six months ended September 30, 2021 decreased by 2.9% compared to the six months ended September 30, 2020, in which revenue was boosted by one-off shipments (-9.5% excluding FX impact), to ¥8.7 billion. Revenue of major products are as follows.

Glaucoma and ocular hypertension		
Tapros ophthalmic solution	¥1.0 billion	(YoY +3.0%)
Tapcom ophthalmic solution	¥0.4 billion	(YoY +63.2%)
Cosopt ophthalmic solution	¥2.5 billion	(YoY +17.3%)
Dry Eye		
Diquas ophthalmic solution	¥0.9 billion	(YoY +8.9%)
Bacterial conjunctivitis		
Cravit ophthalmic solution	¥0.9 billion	(YoY -20.4%)

◇ EMEA

On a JPY basis, revenue in the six months ended September 30, 2021 increased by 13.6% year-on-year (+5.3% excluding FX impact), to ¥20.5 billion. Revenue of major products are as follows.

Glaucoma and ocular hypertension		
	Tapros ophthalmic solution	¥3.3 billion (YoY +0.4%)
	Tapcom ophthalmic solution	¥1.7 billion (YoY +18.7%)
	Cosopt ophthalmic solution	¥5.3 billion (YoY +9.7%)
	Trusopt ophthalmic solution	¥1.5 billion (YoY +6.8%)
Dry Eye		
	Ikervis	¥2.5 billion (YoY +49.1%)

◇ Americas

On a JPY basis, revenue in the six months ended September 30, 2021 was ¥1.5 billion. Revenue from Eyevance Pharmaceuticals Holdings Inc. (U.S.) which Santen acquired in the second quarter of the fiscal year ended March 31, 2021 was ¥1.0 billion.

<OTC pharmaceuticals>

Revenue in the six months ended September 30, 2021 increased by 1.7% year-on-year to ¥5.1 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, which is marking its 30th anniversary since launch this year.

<Medical devices>

Revenue in the six months ended September 30, 2021 increased by 44.5% year-on-year to ¥2.5 billion.
Revenue of major products are as follows:

Lentis Comfort	¥0.7 billion (YoY +43.9%)
PRESERFLO MicroShunt	¥0.7 billion (YoY +104.5%)

<Others>

Other revenues amounted to ¥0.8 billion. This is due to sales of supplements, and cleaning of dustless and aseptic clothing at consolidated subsidiary Clair Co., Ltd.

[Operating profit]

Gross profit in the six months ended September 30, 2021 increased by 9.7 % year-on-year to ¥75.9 billion.
SG&A expenses on an IFRS basis increased by 19.3% year-on-year to ¥39.7 billion. In addition to SG&A expenses on a core basis of ¥39.2 billion to be hereinafter described, expenses of ¥0.4 billion were incurred including one-time expenses in connection with the integration of Eyevance Pharmaceuticals Inc. (U.S.).
R&D expenses in the six months ended September 30, 2021 increased by 10.9% year-on-year to ¥12.3 billion.
Amortization on intangible assets associated with products in the six months ended September 30, 2021 decreased by 1.9% year-on-year to ¥4.8 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, STN2000100 (DE-128, PRESERFLO MicroShunt) acquired in connection with the acquisition of InnFocus, Inc. (U.S.) in 2016 (amortization began in April 2019) and ophthalmic products acquired in connection with the acquisition of Eyevance Pharmaceuticals Holdings Inc. (U.S.) in 2020.

Related to the acquisition of Eyevance Pharmaceuticals Holdings Inc. (U.S.) in 2Q of the fiscal year ended March 2021, as a result of the completion of the purchase price allocation in the six months ended September 2021, the provisional figures used previously have been retroactively restated. Please see section 2. (5) Notes to Condensed Interim Consolidated Financial Statements (Business Combinations) for more details. Note the impact on the condensed interim consolidated financial statement net income and other comprehensive income for the six months ended September 2020 is negligible. The amortization expense for intangible assets related to products in the six months ended September 2021 amounted to ¥0.9 billion.

Other income amounted to ¥0.2 billion.
Other expenses amounted to ¥0.5 billion.

As a result, operating profit on an IFRS basis in the six months ended September 30, 2021 increased by 0.6 % year-on year to ¥18.8 billion.

[Net profit for the period]
Finance income amounted to ¥0.7 billion.
Finance expenses amounted to ¥0.4 billion.

Share of loss of investments accounted for using equity method amounted to ¥0.6 billion from Twenty Twenty Therapeutics LLC (U.S.), a joint venture with Verily Life Sciences LLC (U.S.).
Income tax expenses amounted to ¥4.1 billion. This was mainly due to a decrease in tax burden rate to 22.5% as a function of the year-on-year decrease in the change in the fair value of contingent consideration, associated with the InnFocus, Inc. (U.S.) acquisition, on which the tax effect is not recognized and other factors.
As a result, quarterly net profit in the period ended September 30, 2021 increased by 4.1% year-on-year to ¥14.3 billion.

[Net profit for the period attributable to owners of the company]
Quarterly net profit attributable to owners of the company in the six months ended September 30, 2021 increased by 3.6% year-on-year to ¥14.3 billion. The ratio to revenue was 11.1%.

*1 Includes Alesion LX
*2 Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

B) Core basis*3

(JPY millions)

	Six months ended September 30, 2020	Six months ended September 30, 2021	Year-on-year change
Revenue	118,905	128,759	8.3%
Core Operating profit	25,690	24,306	(5.4%)
Core Net profit for the period	19,687	18,556	(5.7%)
Core Net profit for the period attributable to owners of the company	19,703	18,586	(5.7%)

[Revenue]

There are no adjustments from the core basis.

[Core operating profit]

There are no adjustments to gross profit from the IFRS basis.
SG&A expenses in the six months ended September 30, 2021 increased by 21.2% year-on-year to ¥39.2 billion. For the adjustments from the IFRS basis, please refer to the aforementioned section on [Operating profit].
There are no adjustments to R&D expenses from the IFRS basis.

As a result, Core operating profit on a core basis in the six months ended September 30, 2021 decreased by 5.4% year-on-year to ¥24.3 billion.

*3 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 ordinary performance. The core basis is calculated by adjusting the following income and expense items, which are deducted from IFRS results, and the related income tax expenses.

- 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
- One-time 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 F2α derivative and a beta-adrenergic receptor blocker. Phase 3 trial started in January 2019 in China.

STN1011700 (DE-117, generic name: omidenepag isopropyl) is an EP2 receptor agonist. The Company filed for marketing approval in November 2020 in the U.S. The product was launched in November 2018 in Japan. The Company successively filed for marketing approval in Asian countries. Launched 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 started in December 2020 in the U.S. A phase 2 trial was completed in Japan. Phase 2 trial (exploratory study) started in September 2021 in Europe.

STN2000100 (DE-128)* is a device for glaucoma. The Company filed for marketing approval in May 2021 in Japan. The device was launched in April 2019 in Europe. The Company successively filed for marketing approval in Asian countries since March 2020, and received approval in September 2021 in Singapore. The Company received a rejection letter in Korea in April 2021 but is considering re-filing.

STN1013001 (DE-130A, generic name: latanoprost) is an ophthalmic emulsion of a prostaglandin F2α derivative. Phase 3 trials started in April 2019 in Europe and Asia.

STN1013900 (AR-13324, generic name: netarsudil dimesylate) is a ROCK inhibitor. Phase 3 trial started in November 2020 in Japan.

*Offered product development, commercialization, and sales rights to Glaukos Corporation (U.S., hereinafter, Glaukos) in Americas, Australia and New Zealand in May 2021. Completed Premarket Approval rolling submission in June 2020. Received feedback from the Food and Drug Administration (FDA) on its assessment at the end of February 2021. Discussions with the FDA are ongoing. Received marketing approval in March 2021 in Canada and in May 2021 in Australia. Preparing for a launch by Glaukos**.**

<Keratoconjunctival disease area including dry eye >

STN1007603 (DE-076C, generic name: ciclosporine) for vernal keratoconjunctivitis was approved and lauched in Europe, Asia, and Canada. A new drug application was accepted in April 2021 in China. In the U.S., a new drug application was accepted in October 2020, and the Company received approval in June 2021.

STN1008903 (DE-089C, generic name: diquafosol sodium) is for the treatment of dry eye. The Company filed for manufacturing and marketing approval in August 2021 in Japan.

STN1010905 (generic name: sirolimus) is for meibomian gland dysfunction. Phase 2a trial started in October 2021 in Japan.

<Retina and uveal disease area>

STN1010900 (DE-109, generic name: sirolimus) is being developed for the treatment of uveitis. An additional phase 3 trial was started in December 2018 in the U.S.

<New disease area>

STN1012700 (DE-127, generic name: atropine sulfate) is a treatment for myopia. Phase 2/3 trial was started in August 2019 in Japan. Phase 1 trial started in September 2021 in China. Phase 2 trial was completed in April 2020 in Asia,

STN1013400 (compound name: AFDX0250BS) is a treatment for myopia. Phase 1 trial was started in July 2021 in Japan.

※ The numbering method for development codes has changed. We show both existing development codes (DE-XXX) and new development codes (STNXXXXXXX). AR-13324 is the development code of Aerie Pharmaceuticals, Inc. (U.S.)

(2) Summary of Financial Position

(I) Assets, equity and liabilities

Total assets at the end of the second quarter of the fiscal year under review amounted to ¥420.4 billion, up ¥15.2 billion from the end of the previous fiscal year. Despite a decrease in trade and other receivables, there was 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 as well as cash and cash equivalents associated with long-term loans, which increased ¥10 billion on the drawdown of loans related to capital expenditures for the aforementioned capacity expansion.

Equity amounted to ¥319.0 billion. There was an increase of ¥9.4 billion from the end of the previous fiscal year ended March 31, 2021, due to an increase in retained earnings.

Liabilities amounted to ¥101.4 billion, up ¥5.8 billion from the end of the previous fiscal year ended March 31, 2021. This was due to the decrease in other current liabilities and income tax payable due to the payment of corporate tax but an increase in financial liabilities from long-term loans.

As a result, the ratio of equity attributable to owners of the company to total assets decreased by 0.5 points from the end of the previous fiscal year ended March 31, 2021 to 76.0%.

(II) Cash Flows

Cash flows from operating activities of the second quarter of the fiscal year under review amounted to ¥27.1 billion. (¥18.4 billion in the six months ended September 30, 2020). This was mainly due to the net profit of ¥14.3 billion (¥13.7 billion in the six months ended September 30, 2020), a decrease in trade and other receivables of ¥9.9 billion, income taxes paid of ¥5.0 billion and depreciation and amortization of ¥8.3 billion.

Cash flows from investing activities amounted to ¥17.1 billion. (¥44.7 billion in the six months ended September 30, 2020). This was mainly due to payment for acquisition of property, plant and equipment and intangible assets amounting to ¥9.8 billion and ¥4.7 billion respectively. Santen has also accelerated its review of its strategic equity holdings: as a result, there was a cash inflow of ¥0.7 billion from the divestment of a single holding in the six months ended September 30, 2021.

Cash flows from financing activities amounted to ¥3.0 billion. (¥6.8 billion in the six months ended September 30, 2020). This was mainly due to proceeds from long-term loans of ¥10.0 billion and cash dividends paid of ¥5.6 billion.

As a result, cash and cash equivalents at the end of the second quarter ended September 30, 2021 increased by ¥13.1billion from the end of the fiscal year ended March 31, 2021 to ¥76.0 billion.

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

The results for the six months of the fiscal year under review have been generally in line with forecasts. No changes have been made to the forecasts of consolidated financial results for the year ending March 31, 2022 announced on May 11, 2021.

2. Condensed Interim Consolidated Financial Statements

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

IFRS (JPY millions)

	Six months ended September 30, 2020	Six months ended September 30, 2021
Revenue	**118,905**	**128,759**
Cost of sales	(49,705)	(52,867)
Gross profit	**69,199**	**75,891**
Selling, general and administrative expenses	(33,242)	(39,652)
Research and development expenses	(11,123)	(12,338)
Amortization on intangible assets associated with products	(4,878)	(4,787)
Other income	350	203
Other expenses	(1,620)	(512)
Operating profit	**18,686**	**18,805**
Finance income	566	672
Finance expenses	(883)	(440)
Share of loss of investments accounted for using equity method	(17)	(643)
Profit before tax	**18,353**	**18,393**
Income tax expenses	(4,655)	(4,139)
Net profit for the period	**13,698**	**14,254**
Other comprehensive income		
Items that will not be reclassified subsequently to profit or loss		
Remeasurements of defined benefit plans	—	—
Net gain on financial assets measured at fair value through other comprehensive income	4,170	(134)
Items that may be reclassified subsequently to profit or loss		
Foreign currency translation adjustments	689	653
Share of other comprehensive income of investments accounted for using equity method	(59)	85
Other comprehensive income	**4,799**	**604**
Total comprehensive income	**18,498**	**14,858**
Profit attributable to		
owners of the company	13,813	14,307
Non-controlling interests	(115)	(53)
Net profit for the period	**13,698**	**14,254**
Total comprehensive income attributable to		
owners of the company	18,620	14,927
Non-controlling interests	(122)	(69)
Total comprehensive income	**18,498**	**14,858**
Earnings per share		
Basic earnings per share (yen)	34.58	35.79
Diluted earnings per share (yen)	34.50	35.73

Core basis (JPY millions)

	Six months ended September 30, 2020	Six months ended September 30, 2021
Revenue	118,905	128,759
Core operating profit	25,690	24,306
Core net profit for the period	19,687	18,556
Basic core earnings per share (yen)	49.33	46.50
Diluted core earnings per share (yen)	49.21	46.41
Core profit attributable to		
owners of the company	19,703	18,586
Non-controlling interests	(16)	(30)
Core net profit for the period	**19,687**	**18,556**

(2) Condensed Interim Consolidated Statements of Financial Position

Assets (JPY millions)

	As of March 31, 2021	As of September 30, 2021
Non-current assets		
Property, plant and equipment	39,489	49,082
Intangible assets	115,808	115,482
Financial assets	31,903	31,683
Net defined benefit assets	1,619	1,209
Investments from application of equity method	5,162	7,362
Deferred tax assets	2,824	2,753
Other non-current assets	2,249	1,682
Total non-current assets	**199,054**	**209,253**
Current assets		
Inventories	41,575	40,311
Trade and other receivables	95,992	86,250
Other financial assets	527	367
Other current assets	5,248	8,218
Cash and cash equivalents	62,888	76,036
Total current assets	**206,231**	**211,182**
Total assets	**405,285**	**420,435**

Equity and liabilities (JPY millions)

	As of March 31, 2021	As of September 30, 2021
Equity		
Equity attributable to owners of the company		
Share capital	8,525	8,538
Capital surplus	8,954	8,860
Treasury shares	(934)	(718)
Retained earnings	273,238	282,296
Other components of equity	20,398	20,656
Total equity attributable to owners of the company	**310,181**	**319,632**
Non-controlling interests	**(535)**	**(603)**
Total equity	**309,646**	**319,029**
Liabilities		
Non-current liabilities		
Financial liabilities	10,141	19,915
Net defined benefit liabilities	1,210	1,180
Provisions	600	618
Deferred tax liabilities	3,626	3,518
Other non-current liabilities	1,514	920
Total non-current liabilities	**17,090**	**26,152**
Current liabilities		
Trade and other payables	38,106	37,810
Other financial liabilities	23,739	23,357
Income tax payable	5,458	4,588
Provisions	819	793
Other current liabilities	10,428	8,706
Total current liabilities	**78,549**	**75,254**
Total liabilities	**95,639**	**101,407**
Total equity and liabilities	**405,285**	**420,435**

(3) Condensed Interim Consolidated Statements of Changes in Equity

Six months ended September 30, 2020 (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, 2020	8,366	8,746	(1,033)	273,422	—	11,150
Comprehensive income						
Net profit for the period				13,813		
Other comprehensive income						4,170
Total comprehensive income	—	—	—	13,813	—	4,170
Transactions with owners						
Issuance of new shares	45	45				
Retirement of treasury shares		(65)	102			
Dividends				(5,592)		
Share-based payments		38				
Total transactions with owners	45	18	102	(5,592)	—	—
Balance at September 30, 2020	8,411	8,763	(931)	281,643	—	15,319

(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, 2020	1,529	—	686	13,364	302,865	(305)	302,560
Comprehensive income							
Net profit for the period				—	13,813	(115)	13,698
Other comprehensive income	696	(59)		4,807	4,807	(8)	4,799
Total comprehensive income	696	(59)	—	4,807	18,620	(122)	18,498
Transactions with owners							
Issuance of new shares			(10)	(10)	80		80
Retirement of treasury shares				—	36		36
Dividends				—	(5,592)		(5,592)
Share-based payments				—	38		38
Total transactions with owners	—	—	(10)	(10)	(5,438)	—	(5,438)
Balance at September 30, 2020	2,225	(59)	676	18,161	316,047	(427)	315,620

Six months ended September 30, 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 for the period				14,307		
Other comprehensive income						(134)
Total comprehensive income	—	—	—	14,307	—	(134)
Transactions with owners						
Issuance of new shares	12	12				
Acquisition of treasury shares			(12)			
Retirement of treasury shares		15	228			
Dividends				(5,598)		
Share-based payments		(121)				
Other				349		(349)
Total transactions with owners	12	(93)	216	(5,249)	—	(349)
Balance at September 30, 2021	8,538	8,860	(718)	282,296	—	10,593

(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 for the period				—	14,307	(53)	14,254
Other comprehensive income	669	85		620	620	(16)	604
Total comprehensive income	669	85	—	620	14,927	(69)	14,858
Transactions with owners							
Issuance of new shares			(13)	(13)	12		12
Acquisition of treasury shares				—	(12)		(12)
Retirement of treasury shares				—	243		243
Dividends				—	(5,598)		(5,598)
Share-based payments				—	(121)		(121)
Other				(349)	—		—
Total transactions with owners	—	—	(13)	(362)	(5,476)	—	(5,476)
Balance at September 30, 2021	9,303	255	505	20,656	319,632	(603)	319,029

(4) Condensed Interim Consolidated Statements of Cash Flows

(JPY millions)

	Six months ended September 30, 2020	Six months ended September 30, 2021
Ⅰ. Cash flows from operating activities:		
Net profit for the period	13,698	14,254
Depreciation and amortization	8,184	8,302
Impairment losses	198	48
Shares of loss (profit) of entities accounted for using equity method	17	643
Finance expenses (income)	(285)	(343)
Income tax expenses	4,655	4,139
Decrease (increase) in trade and other receivables	6,380	9,885
Decrease (increase) in inventories	(4,126)	1,468
Increase (decrease) in trade and other payables	(404)	(338)
Increase (decrease) in provisions and net defined benefit liabilities	462	378
Decrease (increase) in other current assets	(1,751)	(2,705)
Increase (decrease) in accounts payable - bonuses	(811)	(1,516)
Other	(1,022)	(2,439)
Subtotal	25,193	31,777
Interest received	76	136
Dividends received	246	250
Interest paid	(82)	(102)
Income tax paid	(7,005)	(4,966)
Net cash flows from (used in) operating activities	**18,428**	**27,096**
Ⅱ. Cash flows from investing activities:		
Payments for acquisition of investments	(2,452)	(536)
Proceeds from sales of investments	—	746
Payments for acquisition of shares of subsidiaries	(23,834)	—
Payments for acquisition of investments accounted for using equity method	(5,349)	(2,759)
Payments for acquisition of property, plant and equipment	(1,920)	(9,792)
Payments for acquisition of intangible assets	(11,106)	(4,711)
Other	(73)	(4)
Net cash flows from (used in) investing activities	**(44,734)**	**(17,057)**
Ⅲ. Cash flows from financing activities:		
Proceeds from long-term loans	148	10,000
Dividends paid	(5,592)	(5,596)
Repayments of lease obligation	(1,407)	(1,432)
Other	80	(0)
Net cash flows from (used in) financing activities	**(6,771)**	**2,972**
Ⅳ. Net increase (decrease) in cash and cash equivalents	**(33,077)**	**13,011**
Ⅴ. Cash and cash equivalents at the beginning of period	**91,430**	**62,888**
Ⅵ. Effect of exchange rate changes on cash and cash equivalents	**391**	**136**
Ⅶ. Cash and cash equivalents at the end of period	**58,745**	**76,036**

(5) Notes to Condensed Interim Consolidated Financial Statements

(Going Concern Assumption)

Not applicable.

(Business Combinations)

For the Six Months Ended September 30, 2020

(1) Business Combination

(Acquisition of Eyevance Pharmaceuticals Holdings Inc. and Eyevance Pharmaceuticals LLC)

(I) Outline of the Business Combination

A) The name and description of the acquirees

Company name： Eyevance Pharmaceuticals Holdings Inc.
Eyevance Pharmaceuticals LLC

Main business： Advancing ocular health through the development and commercialization of innovative and impactful topical ophthalmic products that enable optimal vision and better quality of life

B) Primary reasons for the business combination

Eyevance develops and commercializes topical ophthalmic products targeting the ocular surface and anterior segment. Within this area of focus, Eyevance currently offers, anti-inflammatory, anti-allergic, anti-fungal, anti-infective/anti-inflammatory fixed combination, and tear lubricant products. Eyevance's current commercialization strategy is supported by a national sales team exclusively targeting ophthalmologists, optometrists, and allergists throughout the U.S.

Through this purchase, Santen Group will quickly establish a business base in the U.S. and sincerely tackle and further contribute to addressing the needs of a greater number of patients by providing greater value. At the same time, Santen will gain access to and a presence in the U.S. market, which will accelerate its global business rollout, Santen aims to achieve even further growth and to contribute to ophthalmic treatments for people around the world.

C) Acquisition date

September 16, 2020 (U.S. time)

D) Acquisition method

The Company acquired all of the shares issued by Eyevance Pharmaceuticals Holdings Inc. (U.S.) for a cash consideration.

Both Eyevance Pharmaceuticals Holdings Inc. and its group company, Eyevance Pharmaceuticals Holdings LLC (U.S.), will become wholly-owned subsidiaries of Santen.

E) Percentage of voting equity interests acquired

100%

(II) The Fair Values of Assets Acquired, Liabilities Assumed and Purchase Consideration Transferred as at the Date of the Acquisition

The Company previously reported provisional amounts because the purchase consideration process had not been completed in the previous fiscal year. Following the completion of the purchase consideration during the second quarter of the fiscal year under review, the fair values of assets acquired, liability assumed and purchase consideration transferred as of the date of the acquisition are as follows.

(JPY millions)

	Provisional fair value
Non-current assets	21,428
Current assets	838
Cash and cash equivalents	1,099
Non-current liabilities	(3,725)
Current liabilities	(564)
Goodwill	5,857
Total	24,933
Cash	24,933
Total consideration transferred	24,933

Note. Goodwill incurred primarily consists of the expected future excess profitability resulting from reasonable estimates. For tax law purposes, this goodwill amount cannot be reported as a loss.

In conjunction with the completion of the purchase price adjustment during the second quarter of the fiscal year under review, the provisional amounts initially disclosed have been revised and retroactively restated. Reflecting this, intangible assets and deferred tax liabilities increased ¥17.063 billion and ¥3.55 billion respectively as of the acquisition date. Goodwill as of the same date decreased by ¥13.705 billion. Note the impact on the condensed interim consolidated financial statement net income and other comprehensive income for the six months ended September 2020 is negligible.

In addition, the statement of financial position for the previous fiscal year has also been retroactively restated reflecting the completion of the purchase price adjustment. Reflecting this, intangible assets and deferred tax liabilities increased ¥17.086 billion and ¥0.336 billion respectively. Goodwill decreased by ¥14.154 billion.

Acquisition-related costs of ¥855 million are included in “Selling, general and administrative expenses.”

(III) Cash flow

(JPY millions)

	Amount
Sum of the fair values of the consideration paid	24,933
Cash and cash equivalents held by the acquired company	(1,099)
Purchase of investment securities of consolidated subsidiaries	23,834

(IV) Impact on the Company's Business Results

Income (loss) from Eyevance Pharmaceuticals Holdings Inc. (U.S.) and Eyevance Pharmaceuticals LLC (U.S.) subsequent to the date of acquisition included in the condensed interim consolidated statements of income and comprehensive income of the second quarter of the previous fiscal year has been omitted due to the lack of materiality.

The impact on the Companies' condensed interim consolidated statements of income and comprehensive income for the six months ended September 30, 2021, assuming the acquisition date had been as of the beginning of the annual reporting period was as follows (excluded from scope of audit).

Revenue : ¥813 million
Net profit before tax : (¥2,323 million)

For the Six Months Ended September 30, 2021
No business combination applicable

(Significant Subsequent Events)

Not applicable.

3. Consolidated Reference

(1) Revenue of Major Products

(JPY millions)

Brand name Generic name/formulation	Therapeutic category	Region	Year ended March 31, 2021				Year ending March 31, 2022			
			Six months ended September 30, 2020 Actual	Changes from the same period of previous year	Year ended March 31, 2021 Actual	Changes from the same period of previous year	Six months ended September 30, 2021 Actual	Changes from the same period of previous year	Year ending March 31, 2021 Forecasts	Changes from the same period of previous year
Cravit levofloxacin/ophthalmic solution	Bacterial conjunctivitis	Total	7,576	(15.8%)	12,650	(16.7%)	6,859	(9.5%)	12,147	(4.0%)
		Japan	1,079	(24.6%)	1,971	(23.3%)	971	(10.0%)	1,592	(19.3%)
		China	4,946	(16.9%)	7,927	(16.6%)	4,415	(10.7%)	7,859	(0.9%)
		Asia	1,098	28.4%	1,722	(0.2%)	874	(20.4%)	1,786	3.7%
		EMEA	454	(40.1%)	1,029	(25.1%)	599	32.1%	910	(11.6%)
Tarivid ofloxacin/ophthalmic solution	Bacterial conjunctivitis	Total	917	17.4%	1,427	(3.1%)	691	(24.6%)	1,215	(14.9%)
		Japan	188	(18.5%)	337	(18.6%)	179	(4.5%)	279	(17.3%)
		China	327	(9.7%)	683	16.8%	406	24.1%	688	0.7%
		Asia	402	113.5%	406	(14.1%)	105	(73.8%)	247	(39.2%)
Tapcom tafluprost-timolol maleate/ combination ophthalmic solution	Glaucoma	Total	2,959	13.2%	6,036	11.7%	3,440	16.3%	6,566	8.8%
		Japan	1,336	3.9%	2,604	3.3%	1,412	5.7%	2,403	(7.7%)
		Asia	230	23.8%	546	42.6%	375	63.2%	763	39.8%
		EMEA	1,393	22.0%	2,886	15.4%	1,653	18.7%	3,399	17.8%
Tapros tafluprost/ophthalmic solution	Glaucoma	Total	9,116	1.0%	17,915	0.1%	9,186	0.8%	20,564	14.8%
		Japan	4,605	(2.3%)	8,709	(4.5%)	4,399	(4.5%)	8,738	0.3%
		China	230	39.4%	602	52.4%	465	101.9%	2,788	362.8%
		Asia	954	(0.8%)	1,907	0.8%	983	3.0%	2,105	10.4%
		EMEA	3,327	4.4%	6,696	3.2%	3,340	0.4%	6,933	3.5%
Cosopt dorzolamide hydrochloride-timolol maleate/combination ophthalmic solution	Glaucoma	Total	10,728	2.5%	20,877	(0.8%)	10,758	0.3%	19,597	(6.1%)
		Japan	3,818	0.7%	6,940	(10.1%)	3,018	(20.9%)	5,173	(25.5%)
		Asia	2,100	3.3%	4,462	10.1%	2,463	17.3%	4,778	7.1%
		EMEA	4,810	3.7%	9,475	2.2%	5,277	9.7%	9,646	1.8%
Timoptol timolol maleate/ ophthalmic solution (* Including Timoptol XE)	Glaucoma	Total	1,131	(11.9%)	2,196	(12.3%)	1,083	(4.3%)	1,859	(15.3%)
		Japan	616	(13.3%)	1,137	(15.7%)	531	(13.8%)	789	(30.6%)
		Asia	119	1.3%	264	17.2%	150	26.1%	294	11.1%
		EMEA	396	(13.2%)	794	(14.5%)	402	1.4%	777	(2.2%)
Trusopt dorzolamide hydrochloride/ ophthalmic solution	Glaucoma	Total	2,262	(0.7%)	4,365	(1.3%)	2,292	1.3%	3,862	(11.5%)
		Japan	670	(4.6%)	1,227	(9.1%)	587	(12.4%)	1,009	(17.8%)
		Asia	178	(21.9%)	344	(16.2%)	194	9.2%	308	(10.7%)
		EMEA	1,415	4.9%	2,794	4.9%	1,511	6.8%	2,546	(8.9%)
Eybelis omidenepag isopropyl/ ophthalmic solution	Glaucoma	Total	1,209	89.8%	2,536	55.7%	1,671	38.2%	3,696	45.7%
		Japan	1,209	89.8%	2,516	54.4%	1,629	34.8%	3,612	43.6%
Alesion epinastine hydrochloride/ ophthalmic solution (* Including Alesion LX)	Allergy	Total	7,694	56.0%	32,752	31.5%	9,567	24.3%	32,368	(1.2%)
		Japan	7,694	56.0%	32,733	31.4%	9,506	23.5%	32,225	(1.6%)
		Asia	–	–	19	–	61	–	143	663.1%
Flumetholon fluorometholone/ ophthalmic solution	Inflammation	Total	1,467	(17.8%)	2,812	(6.2%)	1,711	16.7%	2,961	5.3%
		Japan	495	(20.7%)	1,052	(17.3%)	443	(10.5%)	924	(12.1%)
		China	810	(2.1%)	1,392	12.0%	1,101	35.9%	1,676	20.4%
		Asia	162	(51.5%)	368	(23.5%)	168	3.5%	361	(1.9%)
Pirenoxine Ophthalmic Suspension pirenoxine/ ophthalmic solution	Senile cataract	Total	2,055	(2.6%)	3,995	(1.5%)	2,138	4.1%	4,025	0.7%
		Japan	1,244	(6.2%)	2,391	(4.4%)	1,214	(2.5%)	2,354	(1.5%)
		China	397	7.2%	771	9.6%	431	8.7%	717	(7.1%)
		Asia	414	0.2%	832	(2.3%)	494	19.4%	954	14.6%
Oftan Catachrom cytochrome C, adenosine, nicotinamide/ ophthalmic solution	Senile cataract	Total	1,066	(13.5%)	1,830	(18.3%)	882	(17.3%)	1,767	(3.5%)
		EMEA	1,066	(13.5%)	1,830	(18.3%)	882	(17.3%)	1,767	(3.5%)
Sodium Hyaluronate Ophthalmic Viscoelastic Preparation sodium hyaluronate/ adjuvant for ophthalmic operations	Adjuvant for ophthalmic operations	Total	1,085	(8.3%)	2,189	(18.1%)	1,040	(4.1%)	2,414	10.3%
		Japan	1,085	(8.3%)	2,189	(18.1%)	1,040	(4.1%)	2,414	10.3%
EYLEA aflibercept/ solution for intravitreal injection	Intravitreal VEGF inhibitor	Total	33,293	8.3%	64,454	7.2%	36,475	9.6%	65,038	0.9%
		Japan	33,293	8.3%	64,454	7.2%	36,475	9.6%	65,038	0.9%
Hyalein sodium hyaluronate/ophthalmic solution	Dry eye	Total	9,709	(3.6%)	18,420	4.6%	8,314	(14.4%)	14,932	(18.9%)
		Japan	3,604	(12.3%)	6,967	(11.2%)	3,323	(7.8%)	5,893	(15.4%)
		China	4,774	(2.0%)	9,259	17.9%	4,219	(11.6%)	6,918	(25.3%)
		Asia	1,331	22.5%	2,194	15.2%	773	(41.9%)	2,121	(3.3%)
Diquas diquafosol sodium/ophthalmic solution	Dry eye	Total	7,108	(21.2%)	14,403	(9.8%)	9,186	29.2%	17,935	24.5%
		Japan	6,080	(21.8%)	12,283	(13.8%)	6,651	9.4%	13,249	7.9%
		China	243	200.2%	717	328.6%	1,681	591.4%	2,782	288.3%
		Asia	785	(32.4%)	1,404	(9.2%)	855	8.9%	1,904	35.6%
Ikervis ciclosporin/ophthalmic solution	Dry eye	Total	2,076	17.2%	4,529	17.6%	3,011	45.0%	5,553	22.6%
		Asia	417	15.9%	890	20.6%	537	28.7%	1,368	53.7%
		EMEA	1,660	17.5%	3,638	16.9%	2,475	49.1%	4,184	15.0%
Cationorm	Dry eye	Total	1,605	1.0%	3,062	5.2%	1,635	1.9%	3,420	11.7%
		Asia	125	3.9%	256	(3.3%)	185	47.4%	337	31.7%
		EMEA	1,024	1.6%	1,969	(5.9%)	1,068	4.3%	2,315	17.6%
		US	455	(0.9%)	838	50.9%	382	(16.0%)	768	(8.3%)
Lentis Comfort	Intraocular Lens for Cataract Treatment	Total	464	(2.0%)	1,196	12.3%	668	43.9%	2,058	72.0%
		Japan	464	(2.0%)	1,196	12.3%	668	43.9%	2,058	72.0%
PRESERFLO MicroShunt	Glaucoma implant device	Total	356	107.9%	892	230.0%	728	104.5%	1,500	68.0%
		EMEA	356	107.9%	892	230.0%	728	104.5%	1,440	61.5%
OTC pharmaceuticals		Total	5,004	(25.4%)	9,410	(21.8%)	5,087	1.7%	10,000	6.3%
		Japan	4,827	(26.4%)	9,058	(22.7%)	4,791	(0.7%)	9,700	7.1%
		Asia	177	15.0%	352	12.7%	296	67.1%	300	(14.7%)

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.

(2) Research & Development

As of October 2021

Pipeline Development Status (Clinical Stage)

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
ciclosporin	STN1007603 /DE-076C	Vernal keratoconjunctivitis	Original	U.S.				Jun-2021		
				Japan					Apr-2021	

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 extension for Ikervis in August 2019. Launched in November 2019 in Canada. Received marketing approrval in June 2021 in U.S. and filed for marketing approval in April 2021 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				Aug-2021		

A dry eye treatment which stimulates secretion of mucin and aqueous components from the corneal and conjunctival epithelium. Long-lasting drug. Filed for manufacturing and marketing approval in August 2021 in Japan.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
sirolimus	STN1010900 /DE-109	Uveitis	Original	U.S.						
				Japan						
				Europe						
				Asia					Apr-2015	

An intravitreal injection with immunosuppressive effect, anti-angiogenic effect, etc. Started an additional Phase 3 in December 2018 in the U.S. Filed for marketing approval in April 2015 in Asia.

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. Started P2a in October 2021 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	NDA Filed	Approved	Launched
omidenepag isopropyl	STN1011700 / DE-117	Glaucoma/ Ocular hypertension	Co-development with Ube Industries	U.S.				Nov-2020		
				Japan						Nov-2018
				Asia						Feb-2021

An EP2 receptor agonist with a new mechanism of action. Filed for marketing approval in November 2020 in the U.S. Launched in November 2018 in Japan. Filed successively for marketing approval in Asian countries and launched 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		(Phase 2b)				
				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. Started an additional Phase 2 in December 2020 in the U.S. Completed Phase 2b in Japan. Started Phase 2 (exploratory study) in 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						
				Asia						

Non-selective muscarinic antagonist which reduces juvenile myopia progression. Started Phase 2/3 in August 2019 in Japan. Started Phase 1 in September 2021 in China. Completed P2 in April 2020 in Asia.

—	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
glaucoma implant device	STN2000100* / DE-128	Glaucoma	Original	U.S.				May-2021		
				Europe						Apr-2019
				Asia					Sep-2021	

A drainage implant device designed to lower and sustain intraocular pressure (IOP) for the treatment of primary open-angle glaucoma through the drainage of aqueous humor. Filed for marketing approval in May 2021 in Japan. Launched in Europe in April 2019. Filed successively for marketing approval in Asian countries since March 2020 and received approval in September 2021 in Singapore. Received rejection letter in April 2021 but considering re-filing in Korea.

*License-out to Glaukos in Americas, Australia and New Zealand in May 2021. Completed Premarket Approval rolling submission to the FDA in June 2020 and have received FDA's notification on assessment in the end of February 2021 and continued negotiation in the U.S. Received marketing approval in March 2021 in Canada and in May 2021 in Australia. Glaukos is preparing to launch.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
latanoprost	STN1013001 / DE-130A (Catioprost)	Glaucoma/ Ocular hypertension	Original	Europe						
				Asia						

An ophthalmic emulsion of a prostaglandin F2α derivative, for the treatment of glaucoma and ocular hypertension. Started P3 trials in April 2019 in Europe and Asia.

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 juvenile myopia progression. Reduce mydriasis to selectively inhibit a subtype of receptors. Started Phase1 in July 2021 in Japan.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
netarsudil dimesylate	STN1013900 / AR-13324	Glaucoma / Ocular hypertension	Aerie	Japan						

A ROCK (Rho-associated kinase) inhibitor. Developed and sold by Aerie in the U.S. Started Phase 3 in November 2020 in Japan.

Changes from Q1 FY21 (August 6, 2021)

Dev. Code	Changes
STN1008903 / DE-089C	Filed for manufacturing and marketing approval in August 2021 in Japan.
STN1010905	Started P2a in October 2021 in Japan.
STN1012600 / DE-126	Started Phase 2 (exploratory study) in September 2021 in Europe.
STN1012700 / DE-127	Started Phase 1 in September 2021 in China.
STN2000100 / DE-128	Received approval in September 2021 in Singapore.

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

Capital expenditures (JPY millions)

	Six months ended September 30, 2020	Year ended March 31, 2021	Six months ended September 30, 2021	Year ending March 31, 2022
	Actual			Forecast
Consolidated	3,942	11,281	13,737	30,000

Note: Excluding the increase in right-of-use assets.

Depreciation and amortization (JPY millions)

	Six months ended September 30, 2020	Year ended March 31, 2021	Six months ended September 30, 2021	Year ending March 31, 2022
	Actual			Forecast
Manufacturing cost	1,081	2,267	1,141	2,170
Selling, general and administrative expenses	719	1,533	792	1,970
R&D expenses	306	604	289	680
Consolidated total	2,106	4,404	2,222	4,820

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

Amortization of intangible assets associated with products (JPY millions)

	Six months ended September 30, 2020	Year ended March 31, 2021*1	Six months ended September 30, 2021	Year ending March 31, 2022
	Actual			Forecast
Intangible assets (Merck products)	2,904	5,808	2,870	5,740
Intangible assets (DE-128*2)	1,372	2,725	467	890
Intangible assets (Ikervis)	344	701	371	710
Other	258	1,417	1,078	1,560
Consolidated total	4,878	10,650	4,787	8,900

*1 As a result of the completion of the purchase price allocation related to a business combination in the six months ended September 2021, consolidated earnings for the fiscal year ended March 2021 have been retroactively restated.

*2 PRESERFLO MicroShunt (STN2000100)

Research and development expenses (JPY millions)

	Six months ended September 30, 2020	Year ended March 31, 2021	Six months ended September 30, 2021	Year ending March 31, 2022
	Actual			Forecast
Consolidated	11,123	24,112	12,338	26,000
Percent of revenue	9.4%	9.7%	9.6%	10.0%

(4) FOREX

(JPY)

Exchange rate (yen)	Major currency	2nd quarter ended September 30, 2020	Fiscal year ended March 31, 2021	2nd quarter ended September 30, 2021	Fiscal year ending March 31, 2022 (Forecasts)
	USD	106.72	105.95	110.09	105.00
	EUR	121.54	123.73	131.14	125.00
	CNY	15.21	15.61	17.05	16.50

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.