



Summary of Consolidated Financial Results for the Three Months Ended June 30, 2021 (IFRS)

Listed Company Name:	Santen Pharmaceutical Co.,Ltd
Exchanges Listed:	Tokyo (First section)
Stock Code:	4536
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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 Three Months Ended June 30, 2021

(1) Operating Results (IFRS)

	Three months ended June 30, 2020	Three months ended June 30, 2021	% change
Revenue	57,563	64,986	+12.9%
Operating profit	8,016	9,537	+19.0%
Profit before tax	8,359	9,552	+14.3%
Net profit for the period	6,124	7,367	+20.3%
Net profit for the period attributable to owners of the company	6,189	7,383	+19.3%
Total comprehensive income for the period	8,734	9,550	+9.4%
Basic earnings per share (yen)	15.49	18.47	
Diluted earnings per share (yen)	15.46	18.44	

(Core basis)

	Three months ended June 30, 2020	Three months ended June 30, 2021	% change
Revenue	57,563	64,986	+12.9%
Core operating profit	11,655	11,713	+0.5%
Core net profit for the period	8,807	9,026	+2.5%
Core net profit for the period attributable to owners of the company	8,872	9,036	+1.8%
Basic core earnings per share (yen)	22.21	22.60	
Diluted core earnings per share (yen)	22.16	22.56	

(2) Financial Position

	March 31, 2021	June 30, 2021
Total assets	402,353	397,096
Total equity	307,050	311,041
Total equity attributable to owners of the company	307,585	311,602
Total equity attributable to owners of the company ratio	76.4%	78.5%
Equity per share attributable to owners of the company (yen)	769.67	779.72

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	+221.3%
Profit before tax	41,000	+230.2%
Net profit for the year	30,500	+359.0%
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 2 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)

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

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

June 30, 2021	550,049 shares
March 31, 2021	549,909 shares

(iii) Average number of outstanding shares

First quarter ended June 30, 2021	399,633,324 shares
First quarter ended June 30, 2020	399,371,208 shares

(Note)The number of treasury shares at the end of the period includes shares (18,230 shares at the end of the fiscal year ended March 31, 2021 and 18,230 shares at the first quarter of the fiscal year ending March 31, 2022) 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 August 6, 2021. The materials used in this briefing will be posted on our website.

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1. Summary of Quarterly Consolidated Results

(1) Summary of Consolidated Results

(I) Consolidated Results

A) IFRS basis

(JPY millions)

	Three months ended June 30, 2020	Three months ended June 30, 2021	Year-on-year change
Revenue	57,563	64,986	12.9%
Operating profit	8,016	9,537	19.0%
Net profit for the period	6,124	7,367	20.3%
Net profit for the period attributable to owners of the company	6,189	7,383	19.3%

[Revenue]

Revenue in the three months ended June 30, 2021 increased by 12.9% year-on-year to ¥65.0 billion.

In the mainstay prescription pharmaceuticals business, sales grew globally by 12.3% to ¥61.0 billion. This is mainly due to steady growth in mainstay products despite the impact of drug price revisions in Japan and a turnaround from the impact of the COVID-19 situation in the previous fiscal year.

The breakdown of revenue is as follows:

Upper: Amount

Lower: Year-on-year change

【 】: Year-on-year change excluding FX impact

(JPY millions)

	Japan	China	Asia	EMEA	Americas	Total
Prescription pharmaceuticals	38,952	6,448	4,452	10,351	804	61,008
	11.0%	11.4%	15.3%	10.3%	262.2%	12.3%
	【- %】	【(1.1%)】	【5.7%】	【(0.8%)】	【254.3%】	【8.3%】
OTC pharmaceuticals	2,305	—	139	—	—	2,444
	16.7%	—	106.3%	—	—	19.7%
	7.6%	—	—	93.7%	—	38.3%
Medical devices	695	—	—	353	97	1,145
	7.6%	—	—	93.7%	—	38.3%
	369	12	9	—	—	389
Others	16.3%	(29.6%)	(62.3%)	—	—	9.0%
	42,321	6,460	4,600	10,704	901	64,986
	11.3%	11.2%	16.4%	11.9%	305.8%	12.9%

(NOTE)

Represents revenue from sales to external customers.

Classified into countries or regions based on customer location. China is not included in Asia.

EMEA means Europe, the Middle East and Africa.

<Prescription pharmaceuticals>

◇ Japan

Revenue in the three months ended June 30, 2021 increased by 11.0% year-on-year to ¥39.0 billion.

Revenue of major products are as follows.

Glaucoma and ocular hypertension	
<i>Tapros</i> ophthalmic solution	¥2.3 billion (YoY -3.9%)
<i>Tapcom</i> ophthalmic solution	¥0.7 billion (YoY +5.7%)
<i>Eybelis</i> ophthalmic solution	¥0.8 billion (YoY +36.8%)
Dry Eye	
<i>Diquas</i> ophthalmic solution	¥3.4 billion (YoY +13.0%)
Allergy	
<i>Alesion</i> ophthalmic solution ^{*1} (refer to Page5)	¥5.0 billion (YoY +65.3%)
Intravitreal VEGF inhibitor	
<i>EYLEA</i> (solution for intravitreal injection)	¥18.7 billion (YoY +11.5 %)
	^{*2} (refer to Page5)

◇ China

On a JPY basis, revenue in the three months ended June 30, 2021 increased 11.4% year-on-year (-1.1% excluding FX impact), to ¥6.4 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 mainstay products *Cravit* and *Hyalein* ophthalmic solution revenue was impacted by volume-based purchasing. Revenue of major products are as follows.

Glaucoma and ocular hypertension	
<i>Tapros</i> ophthalmic solution	¥0.3billion (YoY +134.2%)
Dry Eye	
<i>Diquas</i> ophthalmic solution	¥0.7 billion (YoY +886.0%)
<i>Hyalein</i> ophthalmic solution	¥2.1 billion (YoY -8.7%)
Bacterial conjunctivitis	
<i>Cravit</i> ophthalmic solution	¥1.8 billion (YoY -19.7%)

◇ Asia (excluding China)

On a JPY basis, revenue in the three months ended June 30, 2021 increased by 15.3% year-on-year (+5.7% excluding FX impact), to ¥4.5 billion. Revenue of major products are as follows.

Glaucoma and ocular hypertension	
<i>Tapros</i> ophthalmic solution	¥0.5 billion (YoY +6.2%)
<i>Tapcom</i> ophthalmic solution	¥0.2 billion (YoY +42.4%)
<i>Cosopt</i> ophthalmic solution	¥1.2 billion (YoY +18.2%)
Dry Eye	
<i>Diquas</i> ophthalmic solution	¥0.4 billion (YoY -6.5%)
Bacterial conjunctivitis	
<i>Cravit</i> ophthalmic solution	¥0.5 billion (YoY +30.6%)

◇ EMEA

On a JPY basis, revenue in the three months ended June 30, 2021 increased by 10.3% year-on-year (-0.8% excluding FX impact), to ¥10.4 billion. Revenue of major products are as follows.

Glaucoma and ocular hypertension	
<i>Tapros</i> ophthalmic solution	¥1.6 billion (YoY -4.6%)
<i>Tapcom</i> ophthalmic solution	¥0.9 billion (YoY +17.8%)
<i>Cosopt</i> ophthalmic solution	¥2.6 billion (YoY +4.1%)
<i>Trusopt</i> ophthalmic solution	¥0.8 billion (YoY +15.6%)
Dry Eye	
<i>Ikervis</i>	¥1.4 billion (YoY +88.5%)

◇ Americas

On a JPY basis, revenue in the three months ended June 30, 2021 was ¥0.8 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 ¥0.6 billion.

<OTC pharmaceuticals>

Revenue in the three months ended June 30, 2021 increased 19.7% year-on-year to ¥2.4 billion.

Santen continues to focus on high-end products such as the *Sante Medical* series, *Sante Beauteye* series, *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 three months ended June 30, 2021 increased 38.3% year-on-year to ¥1.1 billion.

Steady growth was reported for *Lentis Comfort*, Intraocular Lens in Japan and *PRESERFLO MicroShunt*, device for glaucoma in EMEA.

<Others>

Other revenues amounted to ¥0.4 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 three months ended June 30, 2021 increased by 16.0 % year-on-year to ¥38.1 billion.

SG&A expenses on an IFRS basis in the three months ended June 30, 2021 increased by 31.5% year-on-year to ¥20.4 billion. In addition to SG&A expenses on a core basis of ¥20.2 billion to be hereinafter described, expenses of ¥0.2 billion were incurred including one-time expenses in connection with the integration of Eyevance Pharmaceuticals Inc. (U.S.).

R&D expenses in the three months ended June 30, 2021 increased by 9.0% year-on-year to ¥6.1 billion.

Amortization on intangible assets associated with products in the three months ended June 30, 2021 decreased by 16.7% year-on-year to ¥2.0 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 STN2000100 (DE-128, *PRESERFLO MicroShunt*) acquired in connection with the acquisition of InnFocus, Inc. (U.S.) in 2016 (amortization began in April 2019).

Other income amounted to ¥0.1 billion.

Other expenses amounted to ¥0.0 billion.

As a result, operating profit on an IFRS basis in the three months ended June 30, 2021 increased by 19.0 % year-on-year to ¥9.5 billion.

[Quarterly Net profit]

Finance income amounted to ¥0.6 billion.

Finance expenses amounted to ¥0.3 billion.

Share of loss of investments accounted for using equity method amounted to ¥0.3 billion from Twenty Twenty Therapeutics LLC (U.S.), a joint venture with Verily Life Sciences LLC (U.S.)

Income tax expenses amounted to ¥2.2 billion. This was mainly due to a decrease in tax burden rate 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.

As a result, net profit in the period ended June 30, 2021 increased by 20.3% year-on-year to ¥7.4 billion

[Quarterly net profit attributable to owners of the company]

Quarterly net profit attributable to owners of the company in the three months ended June 30, 2021 increased by 19.3% year-on-year to ¥7.4 billion. The ratio to revenue was 11.4%.

*1 Includes *Alesion LX*

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

B) Core basis*3

(JPY millions)

	Three months ended June 30, 2020	Three months ended June 30, 2021	Year-on-year change
Revenue	57,563	64,986	12.9%
Core operating profit	11,655	11,713	0.5%
Cpre net profit for the period	8,807	9,026	2.5%
Core net profit for the period attributable to owners of the company	8,872	9,036	1.8%

[Revenue]

There are no adjustments from the IFRS basis.

[Core operating profit]

There are no adjustments to gross profit and R&D expenses from the IFRS basis.

SG&A expenses in the three months ended June 30, 2021 increased by 30.1% year-on-year to ¥20.2 billion. For the adjustments from the IFRS basis, please refer to the aforementioned section on [Operating profit].

As a result, operating profit on a core basis in the three months ended June 30, 2021 increased by 0.5% year-on-year to ¥11.7 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 F_{2α} 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. Phase 2b trial was completed in Japan.

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 a rejection letter in Korea in April 2021 ; considering re-filing in Korea.

STN1013001 (DE-130A, generic name: latanoprost) is an ophthalmic emulsion of a prostaglandin F_{2α} 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; preparing for a launch by Glaukos. Received marketing approval in May 2021 in Australia.

<Keratoconjunctival disease area including dry eye >

STN1007603 (DE-076C, generic name: cyclosporine) for vernal keratoconjunctivitis was approved and launched 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. Phase 3 trial was completed 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 for myopia. Phase 2 trial was completed in April 2020 in Asia and Phase 2/3 was started in August 2019 in Japan.

STN1013400 (compound name: AFDX0250BS) is 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 (STNXXXXXXXX). 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 first quarter amounted to ¥397.1 billion, down ¥5.3 billion from the end of the previous fiscal year. Despite an increase in property, plant and equipment and others, there was a decrease in cash and cash equivalents associated with payments including dividends and income tax.

Equity amounted to ¥311.0 billion. There was an increase of ¥4.0 billion from the end of the previous fiscal year ended March 31, 2021. This was due to an increase in other components of equity and retained earnings.

Liabilities amounted to ¥86.1 billion, falling by ¥9.2 billion from the end of the previous fiscal year ended March 31, 2021. This was due to the decrease in trade and other payables and income tax payable due to the payment of corporate tax.

As a result, the ratio of equity attributable to owners of the company to total assets increased by 2.1 points from the end of the previous fiscal year ended March 31, 2021 to 78.5%

(II) Cash Flows

Cash flows from operating activities amounted to ¥2.5 billion. (¥7.4 billion in the three months ended June 30, 2020). This was mainly due to the quarterly profit of ¥7.4 billion (¥6.1 billion in the three months ended June 30, 2020), a decrease of ¥4.7 billion in trade and other payables, a ¥4.1 billion corporate tax payment and ¥3.8 billion of depreciation and amortization.

Cash flows from investing activities amounted to ¥4.9 billion. (¥10.6 billion in the three months ended June 30, 2020). This was mainly due to payment for acquisition of intangible assets of ¥2.6 billion, and payment for acquisition of property, plant and equipment amounting to ¥2.1 billion.

Cash flows from financing activities amounted to ¥6.2 billion. (¥6.0 billion in the three months ended June 30, 2020). This was mainly due to cash dividends paid of ¥5.5 billion.

As a result, cash and cash equivalents at the end of the first quarter ended June 30, 2021 decreased by ¥8.2 billion from the end of the fiscal year ended March 31, 2021 to ¥54.7 billion.

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

The results for the first quarter of the fiscal year under review have generally remained in line with plan. 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 and Major Notes

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

IFRS	(JPY millions)	
	Three months ended June 30, 2020	Three months ended June 30, 2021
Revenue	57,563	64,986
Cost of sales	(24,741)	(26,924)
Gross profit	32,822	38,062
Selling, general and administrative expenses	(15,551)	(20,447)
Research and development expenses	(5,616)	(6,121)
Amortization on intangible assets associated with products	(2,448)	(2,040)
Other income	176	120
Other expenses	(1,367)	(39)
Operating profit	8,016	9,537
Finance income	530	590
Finance expenses	(187)	(277)
Share of loss of investments accounted for using equity method	—	(297)
Profit before tax	8,359	9,552
Income tax expenses	(2,235)	(2,185)
Net profit for the period	6,124	7,367
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	2,752	1,290
Items that may be reclassified subsequently to profit or loss		
Foreign currency translation adjustments	(142)	902
Share of other comprehensive income of investments accounted for using equity method	—	(8)
Other comprehensive income	2,610	2,183
Total comprehensive income	8,734	9,550
Profit attributable to		
Owners of the company	6,189	7,383
Non-controlling interests	(65)	(15)
Net profit for the period	6,124	7,367
Total comprehensive income attributable to		
Owners of the company	8,798	9,576
Non-controlling interests	(64)	(26)
Total comprehensive income	8,734	9,550
Earnings per share		
Basic earnings per share (yen)	15.49	18.47
Diluted earnings per share (yen)	15.46	18.44

Core basis (JPY millions)

	Three months ended June 30, 2020	Three months ended June 30, 2021
Revenue	57,563	64,986
Core operating profit	11,655	11,713
Core net profit for the period	8,807	9,026
Basic core earnings per share (yen)	22.21	22.60
Diluted core earnings per share (yen)	22.16	22.56
Core profit attributable to		
Owners of the company	8,872	9,036
Non-controlling interests	(65)	(10)
Core net profit for the period	8,807	9,026

(2)Condensed Interim Consolidated Statements of Financial Position

Assets	(JPY millions)	
	As of March 31, 2021	As of June 30, 2021
Non-current assets		
Property, plant and equipment	39,489	41,644
Intangible assets	112,876	113,322
Financial assets	31,903	34,025
Retirement benefit asset	1,619	1,391
Investments accounted for using equity method	5,162	4,856
Deferred tax assets	2,824	3,014
Other non-current assets	2,249	1,836
Total non-current assets	196,122	200,089
Current assets		
Inventories	41,575	40,671
Trade and other receivables	95,992	94,039
Other financial assets	527	401
Other current assets	5,248	7,196
Cash and cash equivalents	62,888	54,699
Total current assets	206,231	197,007
Total assets	402,353	397,096

Equity and liabilities

(JPY millions)

	As of March 31, 2021	As of June 30, 2021
Equity		
Share capital	8,525	8,525
Capital surplus	8,954	8,992
Treasury shares	(934)	(934)
Retained earnings	270,757	272,724
Other components of equity	20,283	22,295
Total equity attributable to owners of the company	307,585	311,602
Non-controlling interests	(535)	(561)
Total equity	307,050	311,041
Liabilities		
Non-current liabilities		
Financial liabilities	10,141	10,045
Net defined benefit liabilities	1,210	1,231
Provisions	600	609
Deferred tax liabilities	3,290	5,175
Other non-current liabilities	1,514	836
Total non-current liabilities	16,754	17,897
Current liabilities		
Trade and other payables	38,106	33,743
Other financial liabilities	23,739	22,950
Income tax payable	5,458	2,316
Provisions	819	946
Other current liabilities	10,428	8,203
Total current liabilities	78,549	68,158
Total liabilities	95,303	86,055
Total equity and liabilities	402,353	397,096

(3) Condensed Interim Consolidated Statements of Changes in Equity

Three months ended June 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				6,189		
Other comprehensive income						2,752
Total comprehensive income	—	—	—	6,189	—	2,752
Transactions with owners						
Issuance of new shares	45	45				
Dividends				(5,592)		
Share-based payments		43				
Total transactions with owners	45	88	—	(5,592)	—	—
Balance at June 30, 2020	8,411	8,833	(1,033)	274,018	—	13,902

(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				—	6,189	(65)	6,124
Other comprehensive income	(143)			2,609	2,609	1	2,610
Total comprehensive income	(143)	—	—	2,609	8,798	(64)	8,734
Transactions with owners							
Issuance of new shares			(10)	(10)	80		80
Dividends				—	(5,592)		(5,592)
Share-based payments				—	43		43
Total transactions with owners	—	—	(10)	(10)	(5,470)	—	(5,470)
Balance at June 30, 2020	1,386	—	676	15,963	306,193	(369)	305,824

Three months ended June 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)	270,757	—	11,075
Comprehensive income						
Net profit for the period				7,383		
Other comprehensive income						1,290
Total comprehensive income	—	—	—	7,383	—	1,290
Transactions with owners						
Issuance of new shares			(0)			
Dividends				(5,598)		
Share-based payments		38				
Other				182		(182)
Total transactions with owners	—	38	(0)	(5,416)	—	(182)
Balance at June 30, 2021	8,525	8,992	(934)	272,724	—	12,183

(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	8,519	170	518	20,283	307,585	(535)	307,050
Comprehensive income							
Net profit for the period				—	7,383	(15)	7,367
Other comprehensive income	912	(8)		2,194	2,194	(11)	2,183
Total comprehensive income	912	(8)	—	2,194	9,576	(26)	9,550
Transactions with owners							
Issuance of new shares				—	(0)		(0)
Dividends				—	(5,598)		(5,598)
Share-based payments				—	38		38
Other				(182)	—		—
Total transactions with owners	—	—	—	(182)	(5,560)	—	(5,560)
Balance at June 30, 2021	9,431	162	518	22,295	311,602	(561)	311,041

(4) Condensed Interim Consolidated Statements of Cash Flows

(JPY millions)

	Three months ended June 30, 2020	Three months ended June 30, 2021
I. Cash flows from operating activities:		
Net profit for the period	6,124	7,367
Depreciation and amortization	4,116	3,814
Impairment losses	114	7
Shares of loss (profit) of entities accounted for using equity method	—	297
Finance expenses (income)	(242)	(273)
Income tax expenses	2,235	2,185
Decrease (increase) in trade and other receivables	4,923	2,133
Decrease (increase) in inventories	(3,235)	1,242
Increase (decrease) in trade and other payables	1,210	(4,662)
Increase (decrease) in provisions and net defined benefit liabilities	322	368
Increase (decrease) in accounts payable - bonuses	(2,753)	(3,746)
Other	491	(2,341)
Subtotal	13,304	6,391
Interest received	23	48
Dividends received	243	248
Interest paid	(39)	(52)
Income tax paid	(6,086)	(4,094)
Net cash flows from (used in) operating activities	7,445	2,540
II. Cash flows from investing activities:		
Payments for acquisition of investments	(2,202)	(523)
Proceeds from sales of investments	—	383
Payments for acquisition of property, plant and equipment	(1,330)	(2,126)
Payments for acquisition of intangible assets	(7,024)	(2,614)
Other	(8)	(2)
Net cash flows from (used in) investing activities	(10,564)	(4,882)
III. Cash flows from financing activities:		
Proceeds from long-term loans	113	—
Dividends paid	(5,520)	(5,512)
Repayments of lease obligation	(684)	(661)
Other	80	(0)
Net cash flows from (used in) financing activities	(6,012)	(6,173)
IV. Net increase (decrease) in cash and cash equivalents	(9,130)	(8,515)
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	46	326
VII. Cash and cash equivalents at the end of period	82,346	54,699

**(5) Notes for Condensed Interim Consolidated Financial Statements
(Going Concern Assumption)**

Not 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			
			Three months ended June 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	Three months ended June 30, 2021 Actual	Changes from the same period of previous year	Year ending March 31, 2022 Forecast	Changes from the same period of previous year
Cravit levofloxacin/ophthalmic solution	Bacterial conjunctivitis	Total	3,291	(27.7%)	12,650	(16.7%)	3,063	(6.9%)	12,147	(4.0%)
		Japan	521	(27.8%)	1,971	(23.3%)	488	(6.4%)	1,592	(19.3%)
		China	2,186	(27.1%)	7,927	(16.6%)	1,754	(19.7%)	7,859	(0.9%)
		Asia	386	(13.7%)	1,722	(0.2%)	505	30.6%	1,786	3.7%
		EMEA	197	(48.6%)	1,029	(25.1%)	316	60.3%	910	(11.6%)
Tarivid ofloxacin/ophthalmic solution	Bacterial conjunctivitis	Total	319	(22.1%)	1,427	(3.1%)	386	21.1%	1,215	(14.9%)
		Japan	89	(20.6%)	337	(18.6%)	87	(1.7%)	279	(17.3%)
		China	149	(17.0%)	683	16.8%	213	43.4%	688	0.7%
		Asia	82	(31.4%)	406	(14.1%)	86	5.4%	247	(39.2%)
Tapcom tafluprost-timolol maleate/ combination ophthalmic solution	Glaucoma	Total	1,529	12.7%	6,036	11.7%	1,747	14.3%	6,566	8.8%
		Japan	685	2.5%	2,604	3.3%	724	5.7%	2,403	(7.7%)
		Asia	122	24.1%	546	42.6%	173	42.4%	763	39.8%
		EMEA	722	22.4%	2,886	15.4%	850	17.8%	3,399	17.8%
Tapros tafluprost/ophthalmic solution	Glaucoma	Total	4,672	0.2%	17,915	0.1%	4,683	0.2%	20,564	14.8%
		Japan	2,372	(1.0%)	8,709	(4.5%)	2,281	(3.9%)	8,738	0.3%
		China	114	33.8%	602	52.4%	266	134.2%	2,788	362.8%
		Asia	461	(8.1%)	1,907	0.8%	490	6.2%	2,105	10.4%
		EMEA	1,725	2.8%	6,696	3.2%	1,646	(4.6%)	6,933	3.5%
Cosopt dorzolamide hydrochloride-timolol maleate/combination ophthalmic solution	Glaucoma	Total	5,609	3.9%	20,877	(0.8%)	5,437	(3.1%)	19,597	(6.1%)
		Japan	2,042	3.3%	6,940	(10.1%)	1,576	(22.8%)	5,173	(25.5%)
		Asia	1,050	0.2%	4,462	10.1%	1,240	18.2%	4,778	7.1%
		EMEA	2,516	6.0%	9,475	2.2%	2,621	4.1%	9,646	1.8%
Timoptol timolol maleate/ ophthalmic solution (* Including Timoptol XE)	Glaucoma	Total	614	(9.9%)	2,196	(12.3%)	565	(8.1%)	1,859	(15.3%)
		Japan	322	(14.7%)	1,137	(15.7%)	283	(12.0%)	789	(30.6%)
		Asia	92	35.4%	264	17.2%	78	(16.0%)	294	11.1%
		EMEA	200	(15.2%)	794	(14.5%)	204	1.9%	777	(2.2%)
Trusopt dorzolamide hydrochloride/ ophthalmic solution	Glaucoma	Total	1,082	(6.7%)	4,365	(1.3%)	1,169	8.1%	3,862	(11.5%)
		Japan	350	(3.2%)	1,227	(9.1%)	310	(11.7%)	1,009	(17.8%)
		Asia	67	(42.7%)	344	(16.2%)	92	37.5%	308	(10.7%)
		EMEA	664	(2.3%)	2,794	4.9%	768	15.6%	2,546	(8.9%)
Eybelis omidenedipag isopropyl/ ophthalmic solution	Glaucoma	Total	589	106.6%	2,536	55.7%	823	39.6%	3,696	45.7%
		Japan	589	106.6%	2,516	54.4%	806	36.8%	3,612	43.6%
Alesion epinastine hydrochloride/ ophthalmic solution (* Including Alesion LX)	Allergy	Total	3,047	43.8%	32,752	31.5%	5,065	66.2%	32,368	(1.2%)
		Japan	3,047	43.8%	32,733	31.4%	5,038	65.3%	32,225	(1.6%)
		Asia	—	—	19	—	28	—	143	663.1%
Flumetholon fluorometholone/ ophthalmic solution	Inflammation	Total	650	(19.6%)	2,812	(6.2%)	834	28.4%	2,961	5.3%
		Japan	242	(20.8%)	1,052	(17.3%)	222	(8.1%)	924	(12.1%)
		China	325	(14.7%)	1,392	12.0%	528	62.5%	1,676	20.4%
		Asia	83	(31.9%)	368	(23.5%)	84	1.1%	361	(1.9%)
Pirenoxine Ophthalmic Suspension pirenoxine/ ophthalmic solution	Senile cataract	Total	974	(2.6%)	3,995	(1.5%)	1,077	10.6%	4,025	0.7%
		Japan	616	(4.8%)	2,391	(4.4%)	617	0.2%	2,354	(1.5%)
		China	189	27.9%	771	9.6%	222	17.4%	717	(7.1%)
		Asia	169	(17.5%)	832	(2.3%)	238	40.6%	954	14.6%
Oftan Catachrom cytochrome C, adenosine, nicotinamide/ ophthalmic solution	Senile cataract	Total	870	47.8%	1,830	(18.3%)	379	(56.4%)	1,767	(3.5%)
		EMEA	870	47.8%	1,830	(18.3%)	379	(56.4%)	1,767	(3.5%)
Sodium Hyaluronate Ophthalmic Viscoelastic Preparation sodium hyaluronate/ adjuvant for ophthalmic operations	Adjuvant for ophthalmic operations	Total	527	(7.0%)	2,189	(18.1%)	544	3.0%	2,414	10.3%
		Japan	527	(7.0%)	2,189	(18.1%)	544	3.0%	2,414	10.3%
EYLEA afibercept/ solution for intravitreal injection	Intravitreal VEGF inhibitor	Total	16,802	10.9%	64,454	7.2%	18,727	11.5%	65,038	0.9%
		Japan	16,802	10.9%	64,454	7.2%	18,727	11.5%	65,038	0.9%
Hyalain sodium hyaluronate/ophthalmic solution	Dry eye	Total	4,523	(8.6%)	18,420	4.6%	4,251	(6.0%)	14,932	(18.9%)
		Japan	1,815	(15.2%)	6,967	(11.2%)	1,721	(5.2%)	5,893	(15.4%)
		China	2,349	(2.8%)	9,259	17.9%	2,145	(8.7%)	6,918	(25.3%)
		Asia	359	(8.4%)	2,194	15.2%	386	7.6%	2,121	(3.3%)
Diquas diqafosol sodium/ophthalmic solution	Dry eye	Total	3,551	(19.9%)	14,403	(9.8%)	4,537	27.8%	17,935	24.5%
		Japan	3,012	(16.4%)	12,283	(13.8%)	3,402	13.0%	13,249	7.9%
		China	71	132.3%	717	328.6%	697	886.0%	2,782	288.3%
		Asia	468	(41.4%)	1,404	(9.2%)	438	(6.5%)	1,904	35.6%
Ikervis ciclosporin/ophthalmic solution	Dry eye	Total	939	2.1%	4,529	17.6%	1,656	76.3%	5,553	22.6%
		Asia	191	11.8%	890	20.6%	246	28.5%	1,368	53.7%
		EMEA	748	(0.1%)	3,638	16.9%	1,410	88.5%	4,184	15.0%
Cationorm	Dry eye	Total	672	(6.0%)	3,062	5.2%	829	23.4%	3,420	11.7%
		Asia	71	50.3%	256	(3.3%)	103	45.7%	337	31.7%
		EMEA	438	(12.3%)	1,969	(5.9%)	532	21.3%	2,315	17.6%
		North America	163	(2.8%)	838	50.9%	194	19.2%	768	(8.3%)
Lentis Comfort	Intraocular Lens for Cataract Treatment	Total	215	17.4%	1,196	12.3%	341	58.8%	2,058	72.0%
		Japan	215	17.4%	1,196	12.3%	341	58.8%	2,058	72.0%
PRESERFLO MicroShunt	Glaucoma implant device	Total	174	99.4%	892	230.0%	347	99.5%	1,500	68.0%
		Japan	174	99.4%	892	230.0%	347	99.5%	1,440	61.5%
OTC pharmaceuticals		Total	2,043	(45.0%)	9,410	(21.8%)	2,444	19.7%	10,000	6.3%
		Japan	1,975	(45.7%)	9,058	(22.7%)	2,305	16.7%	9,700	7.1%
		Asia	67	(11.2%)	352	12.7%	139	106.3%	300	(14.7%)

* Forecasts in this report are based on 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 July 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	
				China					Apr-2021	
<p>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 approval in June 2021 in U.S. and filed for marketing approval in April 2021 in China.</p>										

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						
<p>A dry eye treatment which stimulates secretion of mucin and aqueous components from the corneal and conjunctival epithelium. Long-lasting drug. Completed Phase 3 in Japan.</p>										

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	
<p>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.</p>										

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						
<p>A fixed dose combination drug of a prostaglandin F_{2α} 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.</p>										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
omidenepeg isopropyl	STN1011700 /DE-117	Glaucoma/ Ocular hypertension	Co-development with Ube Industries	U.S.					Nov-2020	
				Europe						Nov-2018
				Asia					Feb-2021	
<p>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.</p>										

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)	
<p>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.</p>										

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)	
				Asia						
<p>Non-selective muscarinic antagonist which reduces juvenile myopia progression. Started Phase 2/3 in August 2019 in Japan. Completed Phase 2 in April 2020 in Asia.</p>										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
— glaucoma implant device	STN2000100* /DE-128	Glaucoma	Original	Japan					May-2021	
				Europe						Apr-2019
				Asia					Mar-2020	
<p>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. Received a rejection letter in Korea in April 2021; Considering re-filing.</p>										

*Offered product development, commercialization, and sales rights to 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; preparing for a launch by Glaukos. Received marketing approval in May 2021 in Australia.

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	Filed	Approved	Launched
latanoprost	STN1013001 /DE-130A (Catioprost)	Glaucoma/ Ocular hypertension	Original	Europe						
				Asia						
An ophthalmic emulsion of a prostaglandin F _{2α} derivative, for the treatment of glaucoma and ocular hypertension. Started Phase 3 trials in April 2019 in Europe and Asia.										

Compound name	Dev. code	Indication	Original/Licensors	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/Licensors	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 marketed by Aerie in the U.S. Started Phase 3 in November 2020 in Japan.										

Changes from Q4 FY20 (May 11, 2021)

Dev. code	Changes
STN1007603 /DE-076C	Received marketing approval in June 2021 in U.S.
STN2000100 /DE-128	Filed for marketing approval in May 2021 in Japan.
STN1013400	Started Phase1 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 (STNXXXXXXXX). AR-13324 is development code of Aerie Pharmaceuticals, Inc. (U.S.)

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

Capital expenditures (JPY millions)

	Three months ended June 30, 2020	Year ended March 31, 2021	Three months ended June 30, 2021	Year ending March 31, 2022
	Actual			Forecast
Consolidated	2,057	11,281	4,438	30,000

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

Depreciation and amortization (JPY millions)

	Three months ended June 30, 2020	Year ended March 31, 2021	Three months ended June 30, 2021	Year ending March 31, 2022
	Actual			Forecast
Manufacturing cost	670	2,267	587	2,170
Selling, general and administrative expenses	339	1,533	394	1,970
R&D expenses	159	604	144	680
Consolidated total	1,105	4,404	1,125	4,820

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)

	Three months ended June 30, 2020	Year ended March 31, 2021	Three months ended June 30, 2021	Year ending March 31, 2022
	Actual			Forecast
Intangible assets (Merck products)	1,452	5,808	1,452	5,740
Intangible assets (DE-128*)	691	2,725	233	890
Intangible assets (Ikervis)	168	701	187	710
Other	137	687	168	1,560
Consolidated total	2,448	9,920	2,040	8,900

*PRESERFLO MicroShunt

Research and development expenses (JPY millions)

	Three months ended June 30, 2020	Year ended March 31, 2021	Three months ended June 30, 2021	Year ending March 31, 2022
	Actual			Forecast
Consolidated	5,616	24,122	6,121	26,000
Percent of revenue	9.8%	9.7%	9.4%	10.0%

(4) FOREX

(JPY)

Exchange rate (yen)	Major currency	The 1st quarter ended June 30, 2020	Fiscal year ended March 31, 2021	The 1st quarter ended June 30, 2021	Fiscal year ending March 31, 2022 (Forecasts)
		US dollar	107.46	105.95	109.81
Euro	118.69	123.73	132.05	125.00	
CNY	15.13	15.61	17.03	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 changes to the business environment and others.