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Santen Pharmaceutical Co., Ltd.

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First Quarter Financial Results for the Fiscal Year Ending March 31, 2020 [IFRS] (Consolidated)

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(JPY millions)

1. Consolidated performance for the three months ended June 30, 2019

(1) Operating results (Core basis *1)

	Three months ended June 30, 2018	Three months ended June 30, 2019	% change
Revenue	56,483	59,136	+4.7%
Core operating profit	11,669	12,794	+9.6%
Core net profit for the period	8,628	9,671	+12.1%
Core net profit for the period attributable to owners of the company	8,631	9,680	+12.2%
Basic core earnings per share (yen)	21.21	24.25	
Diluted core earnings per share (yen)	21.15	24.19	

(IFRS)

	Three months ended June 30, 2018	Three months ended June 30, 2019	% change
Revenue	56,483	59,136	+4.7%
Operating profit	10,016	9,246	(7.7%)
Profit before tax	9,455	9,002	(4.8%)
Net profit for the period	6,852	6,390	(6.7%)
Net profit for the period attributable to owners of the company	6,854	6,399	(6.6%)
Total comprehensive income for the period	7,000	2,423	(65.4%)
Basic earnings per share (yen)	16.85	16.03	
Diluted earnings per share (yen)	16.79	15.99	

(2) Financial position

	March 31, 2019	June 30, 2019
Total assets	391,186	386,304
Total equity	292,572	289,857
Total equity attributable to owners of the company	290,900	288,271
Total equity attributable to owners of the company ratio	74.4%	74.6%
Equity per share attributable to owners of the company (yen)	728.97	722.27

2. Dividends

	Year to March 2019	Year to March 2020	(Forecasts) Year to March 2020
First quarter dividends per share (yen)	—	—	—
Second quarter dividends per share (yen)	13.00	—	13.00
Third quarter dividends per share (yen)	—	—	—
Year-end dividends per share (yen)	13.00	—	13.00
Annual dividends per share (yen)	26.00	—	26.00

3. Consolidated forecasts of results for the year ending March 31, 2020

(Core basis *1)

	Year to March 2020	% change
Revenue	248,000	+6.0%
Core operating profit	51,000	+5.7%
Core net profit for the year	37,700	+4.5%
Basic Core earnings per share (yen)	95.29	

(IFRS)

	Year to March 2020	% change
Revenue	248,000	+6.0%
Operating profit	34,500	(23.5%)
Profit before tax	34,300	(20.4%)
Net profit for the year	23,200	(27.4%)
Basic earnings per share (yen)	58.98	

***Others**

(1) Changes in significant subsidiaries during the term

(changes in designated subsidiaries resulting in adjustment to the scope of consolidation): No

(2) Changes in accounting policies and accounting estimates

- [i] Changes in the accounting policies required by IFRS: Yes
- [ii] Other changes: No
- [iii] Changes in accounting estimates: No

(3) Number of shares outstanding (common stock):

- [i] Number of shares outstanding at the end of period (including treasury shares)
 - June 30, 2019 : 399,844,054
 - March 31, 2019 : 399,782,354
- [ii] Number of treasury shares at the end of period
 - June 30, 2019 : 668,368
 - March 31, 2019 : 663,412
- [iii] Average number of outstanding shares
 - First quarter ended June 30, 2019: 399,095,566
 - First quarter ended June 30, 2018: 406,881,532

(Information regarding the implementation of audit procedures)

This financial report is exempt from audit.

(Information regarding presentation currency)

All financial information presented in Japanese yen has been rounded to the nearest million, except when otherwise indicated.

(Caution)

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, delays in new products launch, currency exchange rate, legislative and regulatory developments.

***1(Core basis)**

Core results are non-IFRS measures that remove non-core items including amortization on intangible assets associated with products, other income and expenses, finance income and expenses, and temporary expenses of selling, general and administrative expenses in order to provide greater transparency on underlying business performance.

Quarterly consolidated statements of income and comprehensive income

IFRS	(JPY millions)	
	Three months ended June 30, 2018	Three months ended June 30, 2019
Revenue	56,483	59,136
Cost of sales	(23,022)	(24,120)
Gross profit	33,461	35,016
Selling, general and administrative expenses	(16,173)	(16,047)
Research and development expenses	(5,619)	(6,174)
Amortization on intangible assets associated with products	(1,739)	(2,477)
Other income	118	101
Other expenses	(33)	(1,172)
Operating profit	10,016	9,246
Finance income	500	441
Finance expenses	(1,060)	(684)
Profit before tax	9,455	9,002
Income tax expenses	(2,604)	(2,612)
Net profit for the period	6,852	6,390
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	(1,327)	(909)
Items that may be reclassified subsequently to profit or loss		
Foreign currency translation adjustments	1,476	(3,058)
Other comprehensive income	149	(3,967)
Total comprehensive income	7,000	2,423
Profit attributable to		
Owners of the company	6,854	6,399
Non-controlling interests	(3)	(9)
Net profit for the period	6,852	6,390
Total comprehensive income attributable to		
Owners of the company	7,028	2,509
Non-controlling interests	(27)	(86)
Total comprehensive income	7,000	2,423
Earnings per share		
Basic earnings per share (yen)	16.85	16.03
Diluted earnings per share (yen)	16.79	15.99

Core basis (JPY millions)

	Three months ended June 30, 2018	Three months ended June 30, 2019
Revenue	56,483	59,136
Core operating profit	11,669	12,794
Core net profit for the period	8,628	9,671
Basic core earnings per share (yen)	21.21	24.25
Diluted core earnings per share (yen)	21.15	24.19
Core profit attributable to		
Owners of the company	8,631	9,680
Non-controlling interests	(3)	(9)
Core net profit for the period	8,628	9,671

Quarterly consolidated statement of financial position

Assets	(JPY millions)	
	March 31, 2019	June 30, 2019
Non-current assets		
Property, plant and equipment	31,699	39,144
Intangible assets	131,110	127,243
Financial assets	30,044	27,864
Deferred tax assets	1,771	1,743
Other non-current assets	1,819	1,982
Total non-current assets	196,444	197,976
Current assets		
Inventories	35,235	33,738
Trade and other receivables	84,618	82,349
Other financial assets	267	395
Other current assets	3,826	4,048
Cash and cash equivalents	70,796	67,798
Total current assets	194,742	188,328
Total assets	391,186	386,304

Equity and liabilities

(JPY millions)

	March 31, 2019	June 30, 2019
Equity		
Share capital	8,252	8,283
Capital surplus	8,661	8,715
Treasury shares	(1,131)	(1,131)
Retained earnings	258,659	260,287
Other components of equity	16,461	12,118
Total equity attributable to owners of the company	290,900	288,271
Non-controlling interests	1,672	1,586
Total equity	292,572	289,857
Liabilities		
Non-current liabilities		
Financial liabilities	23,520	30,178
Net defined benefit liabilities	1,992	2,066
Provisions	1,255	1,256
Deferred tax liabilities	9,389	8,814
Other non-current liabilities	1,795	1,320
Total non-current liabilities	37,951	43,634
Current liabilities		
Trade and other payables	32,079	27,189
Other financial liabilities	12,116	13,865
Income tax payable	7,185	3,273
Provisions	717	815
Other current liabilities	8,566	7,671
Total current liabilities	60,663	52,812
Total liabilities	98,614	96,447
Total equity and liabilities	391,186	386,304

Quarterly consolidated statement of changes in equity

Three months ended June 30, 2018

(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, 2018	8,032	8,657	(11)	249,225	—	14,364
Comprehensive income						
Net profit for the period				6,854		
Other comprehensive income						(1,327)
Total comprehensive income	—	—	—	6,854	—	(1,327)
Transactions with owners						
Issuance of new shares	29	29				
Acquisition of treasury shares			(1)			
Dividends				(5,289)		
Total transactions with owners	29	29	(1)	(5,289)	—	—
Balance at June 30, 2018	8,061	8,687	(12)	250,790	—	13,037

(JPY millions)

	Other components of equity			Total equity attributable to owners of the company	Non-controlling interests	Total equity
	Foreign currency translation adjustments	Subscription rights to shares	Total			
Balance at April 1, 2018	4,583	975	19,921	285,823	1,734	287,557
Comprehensive income						
Net profit for the period			—	6,854	(3)	6,852
Other comprehensive income	1,500		173	173	(25)	149
Total comprehensive income	1,500	—	173	7,028	(27)	7,000
Transactions with owners						
Issuance of new shares		(40)	(40)	18		18
Acquisition of treasury shares			—	(1)		(1)
Dividends			—	(5,289)		(5,289)
Total transactions with owners	—	(40)	(40)	(5,271)	—	(5,271)
Balance at June 30, 2018	6,083	935	20,054	287,580	1,707	289,287

Three months ended June 30, 2019

(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, 2019	8,252	8,661	(1,131)	258,659	—	10,230
Comprehensive income						
Net profit for the period				6,399		
Other comprehensive income						(909)
Total comprehensive income	—	—	—	6,399	—	(909)
Transactions with owners						
Issuance of new shares	31	31				
Acquisition of treasury shares			(0)			
Dividends				(5,189)		
Share-based payments		23				
Other				418		(418)
Total transactions with owners	31	54	(0)	(4,771)	—	(418)
Balance at June 30, 2019	8,283	8,715	(1,131)	260,287	—	8,904

(JPY millions)

	Other components of equity			Total equity attributable to owners of the company	Non-controlling interests	Total equity
	Foreign currency translation adjustments	Subscription rights to shares	Total			
Balance at April 1, 2019	5,428	802	16,461	290,900	1,672	292,572
Comprehensive income						
Net profit for the period			—	6,399	(9)	6,390
Other comprehensive income	(2,981)		(3,890)	(3,890)	(77)	(3,967)
Total comprehensive income	(2,981)	—	(3,890)	2,509	(86)	2,423
Transactions with owners						
Issuance of new shares		(35)	(35)	28		28
Acquisition of treasury shares			—	(0)		(0)
Dividends			—	(5,189)		(5,189)
Share-based payments			—	23		23
Other			(418)	—		—
Total transactions with owners	—	(35)	(452)	(5,138)	—	(5,138)
Balance at June 30, 2019	2,447	768	12,118	288,271	1,586	289,857

Quarterly consolidated statements of cash flows

(JPY millions)

	Three months ended June 30, 2018	Three months ended June 30, 2019
I. Cash flows from operating activities:		
Net profit for the period	6,852	6,390
Depreciation and amortization	2,749	4,122
Finance expenses (income)	(155)	(231)
Income tax expenses	2,604	2,612
Decrease (increase) in trade and other receivables	(1,991)	1,841
Decrease (increase) in inventories	(1,329)	1,361
Increase (decrease) in trade and other payables	(2,581)	(4,885)
Increase (decrease) in provisions and net defined benefit liabilities	(332)	217
Other	(2,296)	(339)
Subtotal	3,521	11,089
Interest received	58	24
Dividends received	257	258
Interest paid	(3)	(59)
Income tax paid	(7,040)	(6,313)
Net cash flows from (used in) operating activities	(3,207)	4,999
II. Cash flows from investing activities:		
Payments for acquisition of investments	(211)	—
Proceeds from sales of investments	—	760
Payments for acquisition of property, plant and equipment	(1,122)	(1,182)
Payments for acquisition of intangible assets	(446)	(924)
Other	(24)	(8)
Net cash flows from (used in) investing activities	(1,802)	(1,355)
III. Cash flows from financing activities:		
Repayments of long-term loans	(1,454)	—
Dividends paid	(5,205)	(5,102)
Other	17	(641)
Net cash flows from (used in) financing activities	(6,642)	(5,743)
IV. Net increase (decrease) in cash and cash equivalents	(11,652)	(2,099)
V. Cash and cash equivalents at the beginning of period	69,283	70,796
VI. Effect of exchange rate changes on cash and cash equivalents	(207)	(899)
VII. Cash and cash equivalents at the end of period	57,425	67,798

Revenue of major pharmaceuticals

(JPY millions)

Brand name Generic name/formulation	Therapeutic category	Region	Year ended March 31, 2019				Year ending March 31, 2020			
			Three months ended June 30, 2018 Actual	Changes from same period of previous year	Year ended March 31, 2019 Actual	Changes from same period of previous year	Three months ended June 30, 2019 Actual	Changes from same period of previous year	Year ending March 31, 2020 Forecasts	Changes from same period of previous year
Cravit levofloxacin/ophthalmic solution	Bacterial conjunctivitis	Total	3,766	0.5%	15,028	0.6%	4,549	20.8%	15,733	4.7%
		Japan	898	(23.6%)	3,175	(22.7%)	722	(19.6%)	2,528	(20.4%)
		China	2,112	12.4%	8,860	10.9%	2,997	41.9%	9,924	12.0%
		Asia	336	19.8%	1,524	23.5%	448	33.5%	1,873	22.9%
		EMEA	420	2.0%	1,468	(9.0%)	384	(8.6%)	1,407	(4.2%)
Tarivid ofloxacin/ophthalmic solution	Bacterial conjunctivitis	Total	358	(24.4%)	1,445	(8.6%)	410	14.6%	1,472	1.9%
		Japan	136	(6.0%)	482	(5.2%)	112	(17.6%)	364	(24.5%)
		China	146	(15.9%)	599	(13.8%)	179	22.6%	581	(3.0%)
		Asia	76	(51.2%)	364	(3.7%)	119	56.5%	527	44.9%
		EMEA	—	—	—	—	—	—	—	—
Tapcom tafluprost-timolol maleate/ combination ophthalmic solution	Glaucoma	Total	1,155	24.9%	4,788	23.0%	1,356	17.4%	5,708	19.2%
		Japan	644	(0.3%)	2,549	2.8%	668	3.8%	2,724	6.9%
		Asia	66	148.8%	308	94.9%	98	49.5%	400	29.7%
		EMEA	445	76.4%	1,930	53.9%	590	32.5%	2,583	33.8%
		EMEA	—	—	—	—	—	—	—	—
Tapros tafluprost/ophthalmic solution	Glaucoma	Total	4,615	2.1%	18,014	1.0%	4,662	1.0%	18,645	3.5%
		Japan	2,414	(4.4%)	9,554	(0.6%)	2,396	(0.7%)	9,135	(4.4%)
		China	38	64.3%	228	54.8%	85	122.2%	370	62.3%
		Asia	484	24.9%	1,857	11.9%	502	3.7%	1,992	7.2%
		EMEA	1,679	5.9%	6,375	(0.8%)	1,678	(0.0%)	7,149	12.1%
Cosopt dorzolamide hydrochloride-timolol maleate/combination ophthalmic solution	Glaucoma	Total	6,129	(0.4%)	21,985	(9.2%)	5,398	(11.9%)	20,341	(7.5%)
		Japan	2,759	(8.2%)	8,919	(21.8%)	1,977	(28.4%)	7,608	(14.7%)
		Asia	937	17.7%	3,675	14.9%	1,047	11.7%	3,745	1.9%
		EMEA	2,432	3.4%	9,392	(2.2%)	2,374	(2.4%)	8,988	(4.3%)
		EMEA	—	—	—	—	—	—	—	—
Timoptol timolol maleate/ ophthalmic solution	Glaucoma	Total	275	(31.6%)	991	(31.7%)	241	(12.4%)	1,350	36.2%
		Japan	139	(40.1%)	494	(37.1%)	114	(18.1%)	454	(8.1%)
		Asia	30	5.6%	113	(2.8%)	41	37.1%	122	8.4%
		EMEA	106	(25.2%)	384	(30.0%)	86	(19.0%)	773	101.5%
		EMEA	—	—	—	—	—	—	—	—
Timoptol XE timolol maleate/ long-acting ophthalmic solution	Glaucoma	Total	513	(14.8%)	1,883	(15.2%)	441	(13.9%)	1,406	(25.3%)
		Japan	323	(17.7%)	1,151	(18.2%)	264	(18.3%)	1,107	(3.8%)
		Asia	28	6.7%	108	2.6%	27	(2.1%)	109	0.8%
		EMEA	162	(11.9%)	624	(12.0%)	150	(7.2%)	190	(69.5%)
		EMEA	—	—	—	—	—	—	—	—
Trusopt dorzolamide hydrochloride/ ophthalmic solution	Glaucoma	Total	1,154	(2.9%)	4,586	(1.9%)	1,159	0.4%	4,530	(1.2%)
		Japan	398	(11.1%)	1,474	(10.2%)	362	(9.0%)	1,359	(7.8%)
		Asia	100	28.9%	415	26.9%	117	16.5%	526	26.6%
		EMEA	656	(1.1%)	2,697	(0.4%)	680	3.7%	2,645	(1.9%)
		EMEA	—	—	—	—	—	—	—	—
EYBELIS Omidenepag Isopropyl/ ophthalmic solution	Glaucoma	Total	—	—	431	—	285	—	2,366	449.0%
		Japan	—	—	431	—	285	—	2,366	449.0%
Alesion epinastine hydrochloride/ ophthalmic solution	Allergy	Total	2,345	(12.0%)	19,445	15.4%	2,120	(9.6%)	21,865	12.4%
		Japan	2,345	(12.0%)	19,445	15.4%	2,120	(9.6%)	21,865	12.4%
Flumetholon fluorometholone/ ophthalmic solution	Inflammation	Total	841	(6.7%)	3,302	(5.6%)	808	(3.9%)	3,293	(0.3%)
		Japan	405	(25.5%)	1,640	(22.4%)	305	(24.6%)	1,432	(12.7%)
		China	318	22.1%	1,231	16.2%	381	19.7%	1,309	6.3%
		Asia	118	22.0%	430	32.6%	122	3.1%	552	28.3%
		EMEA	—	—	—	—	—	—	—	—
Kary Uni pirenoxine/ ophthalmic solution	Senile cataract	Total	1,015	(17.0%)	4,076	(7.6%)	1,000	(1.5%)	4,122	1.1%
		Japan	671	(8.5%)	2,604	(5.0%)	647	(3.6%)	2,597	(0.2%)
		China	169	(2.4%)	760	(14.1%)	148	(12.6%)	756	(0.5%)
		Asia	175	(44.7%)	713	(9.5%)	205	17.6%	768	7.8%
		EMEA	—	—	—	—	—	—	—	—
Ofgan cytochrome C, adenosine, nicotinamide/ ophthalmic solution	Senile cataract	Total	627	(18.8%)	2,397	(11.1%)	589	(6.0%)	2,445	2.0%
		EMEA	627	(18.8%)	2,397	(11.1%)	589	(6.0%)	2,445	2.0%
Opegan Hi sodium hyaluronate/ adjuvant for ophthalmic operations	Adjuvant for ophthalmic operations	Total	542	(12.8%)	2,154	(6.5%)	567	4.7%	2,011	(6.7%)
		Japan	542	(12.8%)	2,154	(6.5%)	567	4.7%	2,011	(6.7%)
Eylea * aflibercept/ solution for intravitreal injection	Intravitreal VEGF inhibitor	Total	13,976	6.6%	56,157	9.0%	15,148	8.4%	58,363	3.9%
		Japan	13,976	6.6%	56,157	9.0%	15,148	8.4%	58,363	3.9%
Hyalein sodium hyaluronate/ophthalmic solution	Dry eye	Total	4,864	3.3%	18,902	4.0%	4,948	1.7%	19,207	1.6%
		Japan	2,287	(23.6%)	8,763	(18.7%)	2,139	(6.5%)	7,152	(18.4%)
		China	1,986	52.8%	7,567	31.3%	2,417	21.7%	9,792	29.4%
		Asia	591	41.7%	2,572	57.3%	392	(33.7%)	2,263	(12.0%)
		EMEA	—	—	—	—	—	—	—	—
Diquas diquafosol sodium/ophthalmic solution	Dry eye	Total	3,678	4.8%	15,367	7.6%	4,434	20.6%	16,866	9.8%
		Japan	3,355	5.2%	13,932	8.7%	3,605	7.4%	15,082	8.3%
		China	—	—	25	—	30	—	235	829.7%
		Asia	322	0.1%	1,409	(3.7%)	799	147.9%	1,549	10.0%
		EMEA	—	—	—	—	—	—	—	—
Ikervis ciclosporin/ophthalmic solution	Dry eye	Total	723	50.8%	3,391	65.5%	920	27.2%	4,091	20.7%
		Asia	82	—	459	570.3%	171	107.7%	917	99.7%
		EMEA	641	34.1%	2,932	48.0%	749	16.8%	3,174	8.3%
Cationorm	Dry eye	Total	604	20.1%	2,512	20.1%	715	18.3%	3,486	38.7%
		Asia	37	(22.9%)	168	(15.8%)	47	28.3%	322	91.8%
		EMEA	515	27.2%	1,989	19.1%	500	(2.9%)	2,634	32.4%
		US	53	3.5%	355	59.1%	168	218.8%	530	49.1%
LENTIS Comfort	Intraocular Lens for Cataract Treatment	Total	—	—	129	—	183	—	2,910	—
		Japan	—	—	129	—	183	—	2,910	—
OTC pharmaceuticals		Total	3,514	(11.7%)	14,223	(2.5%)	3,713	5.6%	15,128	6.4%
		Japan	3,454	(11.8%)	13,930	(2.6%)	3,637	5.3%	14,707	5.6%
		Asia	60	(2.2%)	293	(0.1%)	76	25.5%	421	43.5%

*Co-promoted product (Anti-VEGF Eylea) of Bayer Yakuhin, Ltd. (MAH)

Exchange rate (yen)	Major currency	1st quarter ended June 30, 2018	Fiscal year ended March 31, 2019	1st quarter ended June 30, 2019	Fiscal year to March 31, 2020(Forecasts)
	USD	108.87	110.82	109.86	110.00
	EUR	129.57	128.38	123.06	130.00
	CNY	17.01	16.52	16.14	16.00

*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, etc.

Research & development

As of August 1, 2019

■ Pipeline of prescription pharmaceuticals (Clinical Stage)

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
sirolimus	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 and planning to complete in approx. FY2022 in the U.S. NDA filed in April 2015 in Asia.										
tafluprost/ timolol maleate	DE-111	Glaucoma/ Ocular hypertension	Co-development with AGC	China						
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 and planning to complete in the 1st half of FY2020 in China.										
epinastine hydrochloride	DE-114A	Allergic conjunctivitis	Nippon Boehringer Ingelheim	Japan				Sep-2018		
An H ₁ receptor antagonist with membrane-stabilizing function, as treatment for allergic conjunctivitis. High dose drug. Filed for manufacturing and marketing approval in September 2018 and planning to receive approval by December 2019 in Japan.										
omidenedapag isopropyl	DE-117	Glaucoma/ Ocular hypertension	Co-development with Ube Industries	U.S.						
				Japan					Nov-2018	
				Asia				Apr-2019		
An EP2 receptor agonist with a new mechanism of action. Started Phase 3 in September 2018 and planning to complete in January ~ June 2020 in the U.S. Launched in November 2018 in Japan. Filed for marketing approval in Korea in April 2019 with successive filings in Asian countries and planning to receive approvals starting from the 1st half of FY2020.										
carotuximab	DE-122	Wet Age-related macular degeneration	TRACON Pharmaceuticals	U.S.		(Phase 2a)				
An intravitreal injection of anti-endothelin antibody. Started Phase 2a in July 2017 and planning to complete in the 2nd half of FY2019 for development in the U.S.										
sepetaprost	DE-126	Glaucoma/ Ocular hypertension	ONO PHARMACEUTICAL	U.S.		(Phase 2b)				
				Japan		(Phase 2b)				
A prostaglandin analogue eye drop drug product with a novel mode of action that is both FP and EP3 receptors dual agonist for the treatment of glaucoma and ocular hypertension. Started Phase 2b in July 2017 in the U.S. and Japan.										
atropine sulfate	DE-127	Myopia	Singapore Health Services, Nanyang Technological University	Japan						
				Asia						
Muscarinic antagonist which reduces juvenile myopia progression. Planning to start Phase 2/3 in the 1st half of FY2019 in Japan. Started Phase 2 in November 2017 and planning to complete in the 2nd half of FY2019 in Asia.										
glaucoma implant device	DE-128	Glaucoma	Original	U.S.		(Phase 2/3)				
				Europe						
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. Conducting Phase 2/3 in the U.S. and Europe in advance of application to FDA. Planning to complete PMA rolling submission in 2019 and launch in 2020 in U.S. Received CE Mark in Europe.										

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
ciclosporin	DE-076C (Vekacia)	Vernal keratoconjunctivitis	Original	Europe						Oct-2018
				Asia				Nov-2018		
				Others					Dec-2018	
An ophthalmic emulsion which improves vernal keratoconjunctivitis by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue penetration. Received the Marketing Authorization Application approval from the European Commission Agency in July 2018 and launched in October 2018 in U.K. Filed for marketing approval in November 2018 and planning to receive approval in July ~ December 2019 in Asia. Received marketing approval in December 2018 and planning to launch in 2019 in Canada.										

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
latanoprost	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 in April 2019 and planning to complete in 2021 in Europe and Asia.										

—	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
intraocular lens	MD-16	Cataract	Oculentis	Japan				May-2019		
A toric intraocular lens for correcting astigmatism, which be implanted into an aphakia after cataract surgery. Filed for manufacturing and marketing approval in May 2019 and planning to receive approval in January ~ June 2020 in Japan.										

■ Changes from Q4 FY18 (May 9, 2019)

Dev. code	Changes
MD-16	Filed for manufacturing and marketing approval in May 2019 in Japan.
DE-109	Plan to complete an additional Phase 3 in approx. FY2022 in the U.S.

Other consolidated information

Capital expenditures

(JPY millions)

	Three months ended June 30, 2018	Year ended March 31, 2019	Three months ended June 30, 2019	Year ending March 31, 2020
	Actual			Forecast
Consolidated	1,280	7,220	1,853	10,000

Depreciation and amortization

(JPY millions)

	Three months ended June 30, 2018	Year ended March 31, 2019	Three months ended June 30, 2019	Year ending March 31, 2020
	Actual			Forecast
Manufacturing cost	473	1,872	566	2,140
Selling, general and administrative expenses	375	1,478	372	1,860
R&D expenses	161	631	160	760
Consolidated total	1,009	3,981	1,098	4,760

Note: Excluding amortization on intangible assets associated with products and long-term advance expense.

Amortization on intangible assets associated with products

(JPY millions)

	Three months ended June 30, 2018	Year ended March 31, 2019	Three months ended June 30, 2019	Year ending March 31, 2020
	Actual			Forecast
Intangible assets (Merck products)	1,452	5,808	1,452	5,810
Intangible assets (DE-128*)	--	--	705	2,830
Intangible assets (Ikervis)	183	727	174	740
Other	103	453	146	520
Consolidated total	1,739	6,988	2,477	9,900

* DE-128 (PRESERFLO MicroShunt)

Research and Development expenses

(JPY millions)

	Three months ended June 30, 2018	Year ended March 31, 2019	Three months ended June 30, 2019	Year ending March 31, 2020
	Actual			Forecast
Consolidated	5,619	23,759	6,174	28,000
Percent of revenue	9.9%	10.2%	10.4%	11.3%

*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, etc.