

Press Release



Santen Reports Consolidated Results for Fiscal 2018

May 9, 2019 – Santen Pharmaceutical Co., Ltd. (Osaka, JAPAN, Tokyo Stock Exchange Code 4536) (Santen) today announced consolidated results for the fiscal year ended March 31, 2019 (FY18).

Increased revenue from key products and growth across all three Santen commercial regions of Japan, Asia and EMEA contributed to FY18 consolidated revenue that reached 234.0 billion yen, an increase of 4.0% year-on-year and a record high for the company. In Japan, Santen's prescription ophthalmic pharmaceutical business grew on revenue from key products to 143.0 billion yen, an increase of 1.3%. Revenue increased in Asia and EMEA regions by 19.4% and 3.1%, respectively, in yen terms. Consolidated core operating profit increased 6.3% to reach a record high of 48.2 billion yen.

In FY19, Santen expects continued contributions from key products in Japan and globally. At the same time, the company will continue making strategic investments including in R&D projects to support future growth while also accelerating cost optimization initiatives. Consolidated revenue and core operating profit are forecast to increase by 6.0% and 5.7%, respectively.

Santen strives to generate continued sustainable growth by contributing to the well-being of patients as a leading company specialized in the field of ophthalmology.

Core basis*	FY18 actual (JPY millions)	change (YoY%)	FY19 forecasts (JPY millions)	change (YoY%)
Revenue	234,026	+4.0%	248,000	+6.0%
Core operating profit	48,230	+6.3%	51,000	+5.7%
Core net profit for the period	36,092	+7.9%	37,700	+4.5%
Earnings per share (basic) (yen)	88.89		95.29	

IFRS**	FY18 actual (JPY millions)	change (YoY%)	FY19 forecasts (JPY millions)	change (YoY%)
Revenue	234,026	+4.0%	248,000	+6.0%
Operating profit	45,098	+16.6%	34,500	(23.5%)
Net profit for the period	31,943	(9.4%)	23,200	(27.4%)

* Core basis results adjust IFRS figures by removing non-core items including amortization associated with products, other revenue and expenses, and financial revenue and expenses in order to provide greater transparency on underlying business performance.

** FY18 IFRS operating profit includes a special gain on the sale of former HQ / Osaka plant site of 4 billion yen. FY19 IFRS operating profit includes a special expense expected from raised assumptions regarding DE-128 milestone payment probability based on development progress.

About Santen

As a specialized company dedicated to ophthalmology, Santen carries out research, development, marketing, and sales of pharmaceuticals, over-the-counter products, and medical devices. Santen is the market leader for prescription ophthalmic pharmaceuticals in Japan and its products now reach patients in over 60 countries. With scientific knowledge and organizational capabilities nurtured over a nearly 130-year history, Santen provides products and services to contribute to the well-being of patients, their loved ones and consequently to society. For more information, please visit Santen's website (www.santen.com).

Santen Forward-Looking Statements

Information provided in this news release contains so-called "Forward-Looking Statements". The realizations of these forecasts are subject to risk and uncertainty from various sources. Therefore, please note that the actual results may differ significantly from the forecasts. Business performance and financial condition are subject to the effects of changes in regulations made by the governments of Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.

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(JPY millions)

1. Consolidated performance for the fiscal year ended March 31, 2019

(1) Operating results (Core basis)

	Year to March 2018	Year to March 2019	% change
Revenue	224,942	234,026	+4.0%
Core operating profit	45,378	48,230	+6.3%
Core net profit for the year	33,458	36,092	+7.9%
Core net profit for the year attributable to owners of the company	33,445	36,103	+7.9%
Basic core earnings per share (yen)	82.29	88.89	
Diluted core earnings per share (yen)	82.00	88.62	

(IFRS)

	Year to March 2018	Year to March 2019	% change
Revenue	224,942	234,026	+4.0%
Operating profit	38,691	45,098	+16.6%
Profit before tax	39,261	43,117	+9.8%
Net profit for the year	35,261	31,943	(9.4%)
Net profit for the year attributable to owners of the company	35,247	31,954	(9.3%)
Total comprehensive income for the year	40,725	29,456	(27.7%)
Basic earnings per share (yen)	86.73	78.67	
Diluted earnings per share (yen)	86.42	78.43	
Profit ratio to equity attributable to owners of the company	13.0%	11.1%	
Profit before tax to total assets ratio	10.5%	11.1%	
Operating profit to revenue ratio	17.2%	19.3%	

(2) Financial position

	March 31, 2018	March 31, 2019
Total assets	388,463	391,186
Total equity	287,557	292,572
Total equity attributable to owners of the company	285,823	290,900
Total equity attributable to owners of the company ratio	73.6%	74.4%
Equity per share attributable to owners of the company (yen)	702.54	728.97

(3) Cash flows

	Year to March 2018	Year to March 2019
Cash flows from operating activities	42,843	32,894
Cash flows from investing activities	(8,259)	(2,935)
Cash flows from financing activities	(17,631)	(28,107)
Cash and cash equivalents at end of year	69,283	70,796

2. Dividends

	Year to March 2018	Year to March 2019	(Forecasts) Year to March 2020
Second quarter dividends per share (yen)	13.00	13.00	13.00
Year-end dividends per share (yen)	13.00	13.00	13.00
Annual dividends per share (yen)	26.00	26.00	26.00
Total dividends paid (full-year)	10,571	10,481	—
Payout ratio (consolidated)	30.0%	33.0%	44.1%
Dividends paid on equity attributable to owners of the company (consolidated)	3.9%	3.6%	—

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

(Core basis)

	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%
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

Note: Santen Canada, Inc. has newly become a consolidated subsidiary.

(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)
 - March 31, 2019 : 399,782,354
 - March 31, 2018 : 406,847,515
- [ii] Number of treasury shares at the end of period
 - March 31, 2019 : 663,412
 - March 31, 2018 : 7,411
- [iii] Average number of outstanding shares (during the fiscal year ended March 31)
 - Fiscal year ended March 31, 2019: 406,166,730
 - Fiscal year ended March 31, 2018: 406,415,195

(Reference)

1. Non-Consolidated performance for the fiscal year ended March 31, 2019

(1) Operating results

	Year to March 2018	Year to March 2019	% change
Net sales	171,872	176,208	+2.5%
Operating income	31,298	32,849	+5.0%
Ordinary income	31,689	33,191	+4.7%
Net income	25,435	28,014	+10.1%
Net income per share (yen)	62.58	68.96	
Diluted net income per share (yen)	62.36	68.76	

(2) Financial position

	March 31, 2018	March 31, 2019
Total assets	320,828	321,924
Net assets	265,765	265,400
Equity ratio	82.5%	82.2%
Net assets per share (yen)	650.84	662.95

Reference: Equity at year-end:

Fiscal year ended March 31, 2019: 264,598 million yen

Fiscal year ended March 31, 2018: 264,790 million yen

(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.

Consolidated statements of income and comprehensive income

IFRS	(JPY millions)	
	Year ended March 31, 2018	Year ended March 31, 2019
Revenue	224,942	234,026
Cost of sales	(86,378)	(90,764)
Gross profit	138,564	143,262
Selling, general and administrative expenses	(68,788)	(71,273)
Research and development expenses	(24,398)	(23,759)
Amortization on intangible assets associated with products	(6,740)	(6,988)
Other income	417	4,028
Other expenses	(364)	(172)
Operating profit	38,691	45,098
Finance income	1,004	901
Finance expenses	(434)	(2,881)
Profit before tax	39,261	43,117
Income tax expenses	(4,000)	(11,174)
Net profit for the year	35,261	31,943
Other comprehensive income		
Items that will not be reclassified subsequently to profit of loss		
Remeasurements of defined benefit plans	284	9
Net gain on financial assets measured at fair value through other comprehensive income	5,867	(3,289)
Items that may be reclassified subsequently to profit or loss		
Foreign currency translation adjustments	(686)	794
Other comprehensive income	5,464	(2,486)
Total comprehensive income	40,725	29,456
Profit attributable to		
Owners of the company	35,247	31,954
Non-controlling interests	14	(11)
Net profit for the year	35,261	31,943
Total comprehensive income attributable to		
Owners of the company	40,648	29,519
Non-controlling interests	77	(62)
Total comprehensive income	40,725	29,456
Earnings per share		
Basic earnings per share (yen)	86.73	78.67
Diluted earnings per share (yen)	86.42	78.43

Core basis (JPY millions)

	Year ended March 31, 2018	Year ended March 31, 2019
Revenue	224,942	234,026
Core operating profit	45,378	48,230
Core net profit for the year	33,458	36,092
Basic core earnings per share (yen)	82.29	88.89
Diluted core earnings per share (yen)	82.00	88.62
Core profit attributable to		
Owners of the company	33,445	36,103
Non-controlling interests	14	(11)
Core net profit for the year	33,458	36,092

Consolidated statement of financial position

Assets	(JPY millions)	
	March 31, 2018	March 31, 2019
Non-current assets		
Property, plant and equipment	29,706	31,699
Intangible assets	134,495	131,110
Financial assets	35,775	30,044
Deferred tax assets	2,264	1,771
Other non-current assets	2,855	1,819
Total non-current assets	205,095	196,444
Current assets		
Inventories	30,636	35,235
Trade and other receivables	78,654	84,618
Other financial assets	472	267
Other current assets	4,322	3,826
Cash and cash equivalents	69,283	70,796
Total current assets	183,367	194,742
Total assets	388,463	391,186

Equity and liabilities

(JPY millions)

	March 31, 2018	March 31, 2019
Equity		
Share capital	8,032	8,252
Capital surplus	8,657	8,661
Treasury shares	(11)	(1,131)
Retained earnings	249,225	258,659
Other components of equity	19,921	16,461
Total equity attributable to owners of the company	285,823	290,900
Non-controlling interests	1,734	1,672
Total equity	287,557	292,572
Liabilities		
Non-current liabilities		
Financial liabilities	21,244	23,520
Net defined benefit liabilities	1,804	1,992
Provisions	1,367	1,255
Deferred tax liabilities	12,909	9,389
Other non-current liabilities	1,380	1,795
Total non-current liabilities	38,704	37,951
Current liabilities		
Trade and other payables	29,743	32,079
Other financial liabilities	14,404	12,116
Income tax payable	7,656	7,185
Provisions	1,508	717
Other current liabilities	8,890	8,566
Total current liabilities	62,201	60,663
Total liabilities	100,905	98,614
Total equity and liabilities	388,463	391,186

Consolidated statement of changes in equity

Year ended March 31, 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, 2017	7,792	8,417	(10)	223,283	—	9,470
Comprehensive income						
Net profit for the period				35,247		
Other comprehensive income					284	5,867
Total comprehensive income	—	—	—	35,247	284	5,867
Transactions with owners						
Issuance of new shares	240	240				
Acquisition of treasury shares			(1)			
Dividends				(10,563)		
Changes in equity of subsidiary with non-controlling interests						
Share-based payments						
Other				1,257	(284)	(973)
Total transactions with owners	240	240	(1)	(9,306)	(284)	(973)
Balance at March 31, 2018	8,032	8,657	(11)	249,225	—	14,364

	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, 2017	5,332	825	15,628	255,110	819	255,929
Comprehensive income						
Net profit for the period			—	35,247	14	35,261
Other comprehensive income	(749)		5,401	5,401	63	5,464
Total comprehensive income	(749)	—	5,401	40,648	77	40,725
Transactions with owners						
Issuance of new shares		(68)	(68)	412		412
Acquisition of treasury shares			—	(1)		(1)
Dividends			—	(10,563)		(10,563)
Changes in equity of subsidiary with non-controlling interests			—	—	838	838
Share-based payments		218	218	218		218
Other			(1,257)	—		—
Total transactions with owners	—	150	(1,107)	(9,934)	838	(9,096)
Balance at March 31, 2018	4,583	975	19,921	285,823	1,734	287,557

Year ended March 31, 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, 2018	8,032	8,657	(11)	249,225	—	14,364
Comprehensive income						
Net profit for the period				31,954		
Other comprehensive income					9	(3,289)
Total comprehensive income	—	—	—	31,954	9	(3,289)
Transactions with owners						
Issuance of new shares	152	152				
Acquisition of treasury shares		(148)	(13,911)	—		
Retirement of treasury stock		(12,791)	12,791			
Transfer to Retained earnings from Capital surplus		12,791		(12,791)		
Dividends				(10,581)		
Share-based payments	67	(1)				
Other				853	(9)	(844)
Total transactions with owners	220	4	(1,120)	(22,519)	(9)	(844)
Balance at March 31, 2019	8,252	8,661	(1,131)	258,659	—	10,230

	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			—	31,954	(11)	31,943
Other comprehensive income	845		(2,435)	(2,435)	(51)	(2,486)
Total comprehensive income	845	—	(2,435)	29,519	(62)	29,456
Transactions with owners						
Issuance of new shares		(173)	(173)	132		132
Acquisition of treasury shares			—	(14,059)		(14,059)
Retirement of treasury stock			—	—		—
Transfer to Retained earnings from Capital surplus			—	—		—
Dividends			—	(10,581)		(10,581)
Share-based payments		—	—	67		67
Other			(853)	—		—
Total transactions with owners	—	(173)	(1,025)	(24,442)	—	(24,442)
Balance at March 31, 2019	5,428	802	16,461	290,900	1,672	292,572

Consolidated statements of cash flows

(JPY millions)

	Year ended March 31, 2018	Year ended March 31, 2019
I. Cash flows from operating activities:		
Net profit for the year	35,261	31,943
Depreciation and amortization	10,896	10,969
Impairment losses	150	—
Gain on disposal of non-current assets	—	(3,592)
Finance expenses (income)	(327)	(700)
Income tax expenses	4,000	11,174
Decrease (increase) in trade and other receivables	(7,116)	(6,303)
Decrease (increase) in inventories	(1,435)	(5,000)
Increase (decrease) in trade and other payables	5,697	2,445
Increase (decrease) in provisions and net defined benefit liabilities	285	(518)
Increase (decrease) in accounts payable-other	961	1,181
Increase (decrease) in long-term accounts payable-other	17	1,885
Other	728	2,116
Subtotal	49,117	45,601
Interest received	145	187
Dividends received	598	521
Interest paid	(27)	(8)
Income tax paid	(6,990)	(13,408)
Net cash flows from (used in) operating activities	42,843	32,894
II. Cash flows from investing activities:		
Payments for acquisition of investments	(565)	(931)
Proceeds from sales of investments	2,879	2,156
Payments for acquisition of property, plant and equipment	(3,984)	(5,470)
Proceeds from sales of property, plant and equipment	—	4,338
Payments for acquisition of intangible assets	(5,953)	(2,863)
Other	(636)	(166)
Net cash flows from (used in) investing activities	(8,259)	(2,935)
III. Cash flows from financing activities:		
Proceeds from long-term loans	—	567
Repayments of long-term loans	(8,316)	(4,098)
Purchase of treasury stock	(1)	(14,124)
Capital contribution from non-controlling interests	838	—
Dividends paid	(10,559)	(10,580)
Other	408	128
Net cash flows from (used in) financing activities	(17,631)	(28,107)
IV. Net increase (decrease) in cash and cash equivalents	16,953	1,852
V. Cash and cash equivalents at the beginning of year	52,282	69,283
VI. Effect of exchange rate changes on cash and cash equivalents	48	(338)
VII. Cash and cash equivalents at the end of period	69,283	70,796

Breakdown of revenue

Year ended March 31, 2018

(JPY millions)

Prescription pharmaceuticals	OTC pharmaceuticals	Medical devices	Others	Total
206,967	14,594	2,583	798	224,942

Year ended March 31, 2019

(JPY millions)

Prescription pharmaceuticals	OTC pharmaceuticals	Medical devices	Others	Total
216,030	14,223	2,709	1,065	234,026

Geographic information

Year ended March 31, 2018

(JPY millions)

Japan	EMEA	US	Asia	Total
158,653	35,015	371	30,903	224,942

Year ended March 31, 2019

(JPY millions)

Japan	EMEA	US	Asia	Total
160,456	36,156	533	36,881	234,026

Revenue of major pharmaceuticals

(JPY millions)

Brand name Generic name/formulation	Therapeutic category	Region	Year ended March 31, 2019		Year ending March 31, 2020	
			Year ended March 31 Actual	Changes from same period of previous year	Year ending March 31 Forecasts	Changes from same period of previous year
Cravit levofloxacin/ ophthalmic solution	Bacterial conjunctivitis	Total	15,028	0.6%	15,733	4.7%
		Japan	3,175	(22.7%)	2,528	(20.4%)
		Asia	10,385	12.6%	11,797	13.6%
		EMEA	1,468	(9.0%)	1,407	(4.2%)
Tarivid ofloxacin/ ophthalmic solution	Bacterial conjunctivitis	Total	1,445	(8.6%)	1,472	1.9%
		Japan	482	(5.2%)	364	(24.5%)
		Asia	963	(10.2%)	1,108	15.1%
Tapcom tafluprost-timolol maleate/ combination ophthalmic solution	Glaucoma	Total	4,788	23.0%	5,708	19.2%
		Japan	2,549	2.8%	2,724	6.9%
		Asia	308	94.9%	400	29.7%
		EMEA	1,930	53.9%	2,583	33.8%
Tapros tafluprost/ ophthalmic solution	Glaucoma	Total	18,014	1.0%	18,645	3.5%
		Japan	9,554	(0.6%)	9,135	(4.4%)
		Asia	2,085	15.4%	2,361	13.2%
		EMEA	6,375	(0.8%)	7,149	12.1%
Cosopt dorzolamide hydrochloride-timolol maleate/ combination ophthalmic solution	Glaucoma	Total	21,985	(9.2%)	20,341	(7.5%)
		Japan	8,919	(21.8%)	7,608	(14.7%)
		Asia	3,675	14.9%	3,745	1.9%
		EMEA	9,392	(2.2%)	8,988	(4.3%)
Timoptol timolol maleate/ ophthalmic solution	Glaucoma	Total	991	(31.7%)	1,350	36.2%
		Japan	494	(37.1%)	454	(8.1%)
		Asia	113	(2.8%)	122	8.4%
		EMEA	384	(30.0%)	773	101.5%
Timoptol XE timolol maleate/ long-acting ophthalmic solution	Glaucoma	Total	1,883	(15.2%)	1,406	(25.3%)
		Japan	1,151	(18.2%)	1,107	(3.8%)
		Asia	108	2.6%	109	0.8%
		EMEA	624	(12.0%)	190	(69.5%)
Trusopt dorzolamide hydrochloride/ ophthalmic solution	Glaucoma	Total	4,586	(1.9%)	4,530	(1.2%)
		Japan	1,474	(10.2%)	1,359	(7.8%)
		Asia	415	26.9%	526	26.6%
		EMEA	2,697	(0.4%)	2,645	(1.9%)
Rescula isopropyl unoprostone/ ophthalmic solution	Glaucoma	Total	1,402	(4.4%)	-	-
		Japan	1,402	(4.4%)	-	-
EYBELIS Omidenepag Isopropyl/ ophthalmic solution	Glaucoma	Total	431	-	2,366	449.0%
		Japan	431	-	2,366	449.0%
Alesion epinastine hydrochloride/ ophthalmic solution	Allergy	Total	19,445	15.4%	21,865	12.4%
		Japan	19,445	15.4%	21,865	12.4%
Flumetholon fluorometholone/ ophthalmic solution	Inflammation	Total	3,302	(5.6%)	3,293	(0.3%)
		Japan	1,640	(22.4%)	1,432	(12.7%)
		Asia	1,662	20.0%	1,861	12.0%
		EMEA	-	-	-	-
Kary Uni pirenoxine/ ophthalmic solution	Senile cataract	Total	4,076	(7.6%)	4,122	1.1%
		Japan	2,604	(5.0%)	2,597	(0.2%)
		Asia	1,472	(11.9%)	1,525	3.6%
Oftran Catachrom cytochrome C, adenosine, nicotinamide/ ophthalmic solution	Senile cataract	Total	2,397	(11.1%)	2,445	2.0%
		EMEA	2,397	(11.1%)	2,445	2.0%
Opegan Hi sodium hyaluronate/ adjuvant for ophthalmic operations	Adjuvant for ophthalmic operations	Total	2,154	(6.5%)	2,011	(6.7%)
		Japan	2,154	(6.5%)	2,011	(6.7%)
Eylea * aflibercept/ solution for intravitreal injection	Intravitreal VEGF inhibitor	Total	56,157	9.0%	58,363	3.9%
		Japan	56,157	9.0%	58,363	3.9%
Hyalein sodium hyaluronate/ ophthalmic solution	Dry eye	Total	18,902	4.0%	19,207	1.6%
		Japan	8,763	(18.7%)	7,152	(18.4%)
		Asia	10,139	37.1%	12,055	18.9%
Diquas diquafosol sodium/ ophthalmic solution	Dry eye	Total	15,367	7.6%	16,866	9.8%
		Japan	13,932	8.7%	15,082	8.3%
		Asia	1,434	(2.0%)	1,784	24.4%
Ikervis cyclosporin/ ophthalmic solution	Dry eye	Total	3,391	65.5%	4,091	20.7%
		Asia	459	570.3%	917	99.7%
		EMEA	2,932	48.0%	3,174	8.3%
Cationorm	Dry eye	Total	2,512	20.1%	3,486	38.7%
		Asia	168	(15.8%)	322	91.8%
		EMEA	1,989	19.1%	2,634	32.4%
LENTIS Comfort	Intraocular Lens for Cataract Treatment	Total	129	-	2,910	-
		Japan	129	-	2,910	-
		US	355	59.1%	530	49.1%
OTC pharmaceuticals		Total	14,223	(2.5%)	15,128	6.4%
		Japan	13,930	(2.6%)	14,707	5.6%
		Asia	293	(0.1%)	421	43.5%

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

Exchange rate (yen)	Major currency	Year to March 2018	2nd quarter ended September 30, 2018	Year to March 2019	Year to March 2020 (Forecasts)
	US dollar	110.94	110.21	110.82	110.00
Euro	129.92	129.81	128.38	130.00	
CNY	16.84	16.70	16.52	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 May 9

■ Pipeline of prescription pharmaceuticals (Clinical Stage)

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
diquafosol sodium	DE-089	Dry eye	Merck Sharp & Dohme Corp. (U.S.)	China						Sep-2018
A dry eye treatment which stimulates secretion of mucin and aqueous components from the corneal and conjunctival epithelium. Its mechanism of action is different from existing treatments. Launched in December 2010 in Japan. Launched in October 2013 in Korea. Launched in February 2016 in Vietnam. Launched in April 2016 in Thailand. Currently seeking sequential approvals for marketing in Asia. Launched in September 2018 in China.										
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 January ~ June 2021 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 F2α 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 in July ~ December 2019 in Japan.										
omidenepeg isopropyl	DE-117	Glaucoma/ Ocular hypertension	Co-development with Ube Industries	U.S.						
				Japan					Nov-2018	
				Asia				Apr2019		
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.										

■ Pipeline development status (clinical stage)

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	
<p>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 manufacturing and 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.</p>										

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						
<p>An ophthalmic emulsion of a prostaglandin F_{2α} derivative, for the treatment of glaucoma and ocular hypertension.</p>										

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
intraocular lens	MD-16	Cataract	Oculentis	Japan						
<p>A toric intraocular lens which be implanted into an aphakia after cataract surgery. Completed Phase 3 in April 2019 and planning to file in the 1st half of FY2019 in Japan.</p>										

■ Changes from Q3 FY18 (February 5, 2019)

Dev. code	Changes
DE-117	Filed for marketing approval in Korea in April 2019 with successive filing in Asian countries.
DE-130A	Started Phase 3 in April 2019 in Europe and Asia.
MD-16	Completed Phase 3 in April 2019 in Japan.

Other consolidated information

Capital expenditures

(JPY millions)

	Six months ended September 30, 2018	Year ended March 31, 2019	Year ending March 31, 2020
	Actual		Forecast
Consolidated	3,233	7,220	10,000

Depreciation and amortization

(JPY millions)

	Six months ended September 30, 2018	Year ended March 31, 2019	Year ending March 31, 2020
	Actual		Forecast
Manufacturing cost	946	1,872	2,140
Selling, general and administrative expenses	765	1,478	1,860
R&D expenses	326	631	760
Consolidated total	2,037	3,981	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)

	Six months ended September 30, 2018	Year ended March 31, 2019	Year ending March 31, 2020
	Actual		Forecast
Intangible assets (Merck products)	2,904	5,808	5,810
Intangible assets (DE-128*)	--	--	2,830
Intangible assets (Ikervis)	368	727	740
Other	201	453	520
Consolidated total	3,473	6,988	9,900

* DE-128 (PRESERFLO MicroShunt)

Research and development expenses

(JPY millions)

	Six months ended September 30, 2018	Year ended March 31, 2019	Year ending March 31, 2020
	Actual		Forecast
Consolidated	10,964	23,759	28,000
Percent of revenue	9.6%	10.2%	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.