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Santen Pharmaceutical Co., Ltd.

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First Quarter Financial Results for the Fiscal Year Ending March 31, 2018 [IFRS] (Consolidated)

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(JPY millions)

1. Consolidated performance for the three months ended June 30, 2017

(1) Operating results (Core basis *1)

	Three months ended June 30, 2016	Three months ended June 30, 2017	% change
Revenue	50,006	55,949	+11.9%
Core operating profit	12,353	13,698	+10.9%
Core net profit for the period	8,762	9,991	+14.0%
Core net profit for the period attributable to owners of the company	8,762	9,996	+14.1%
Basic core earnings per share (yen)	21.15	24.61	
Diluted core earnings per share (yen)	21.07	24.52	

(IFRS)

	Three months ended June 30, 2016	Three months ended June 30, 2017	% change
Revenue	50,006	55,949	+11.9%
Operating profit	10,811	12,056	+11.5%
Profit before tax	10,253	12,209	+19.1%
Net profit for the period	7,323	8,915	+21.7%
Net profit for the period attributable to owners of the company	7,323	8,920	+21.8%
Total comprehensive income for the period	1,613	12,022	+645.2%
Basic earnings per share (yen)	17.68	21.96	
Diluted earnings per share (yen)	17.61	21.88	

(2) Financial position

	March 31, 2017	June 30, 2017
Total assets	322,778	325,577
Total equity	253,884	260,636
Total equity attributable to owners of the company	253,065	259,805
Total equity attributable to owners of the company ratio	78.4%	79.8%
Equity per share attributable to owners of the company (yen)	623.06	639.62

2. Dividends

	Year to March 2017	Year to March 2018	(Forecasts) Year to March 2018
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, 2018

(Core basis *1)

	Year to March 2018	% change
Revenue	218,000	+9.5%
Core operating profit	44,000	+10.9%
Core net profit for the year	31,200	+8.8%
Core net profit for the year attributable to owners of the company	31,400	+9.4%
Core earnings per share (yen)	77.31	

(IFRS)

	Year to March 2018	% change
Revenue	218,000	+9.5%
Operating profit	37,400	+15.2%
Profit before tax	37,700	+18.5%
Net profit for the year	26,800	+16.2%
Net profit for the year attributable to owners of the company	26,900	+16.6%
Basic earnings per share (yen)	66.23	

***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: No
- [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, 2017 : 406,190,015
 - March 31, 2017 : 406,173,015
- [ii] Number of treasury shares at the end of period
 - June 30, 2017 : 6,811
 - March 31, 2017 : 6,646
- [iii] Average number of outstanding shares
 - First quarter ended June 30, 2017: 406,176,961
 - First quarter ended June 30, 2016: 414,192,576

(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 basis	(JPY millions)	
	Three months ended June 30, 2016	Three months ended June 30, 2017
Revenue	50,006	55,949
Cost of sales	(18,395)	(21,581)
Gross profit	31,611	34,367
Selling, general and administrative expenses	(14,100)	(15,056)
Research and development expenses	(5,158)	(5,613)
Amortization on intangible assets associated with products	(1,586)	(1,656)
Other income	110	83
Other expenses	(66)	(69)
Operating profit	10,811	12,056
Finance income	427	451
Finance expenses	(985)	(298)
Profit before tax	10,253	12,209
Income tax expenses	(2,930)	(3,294)
Net profit for the period	7,323	8,915
Other comprehensive income		
Items that will not be reclassified subsequently to profit of loss		
Remeasurements of defined benefit plans	—	—
Net gain on financial assets measured at fair value through other comprehensive income	(1,067)	1,478
Items that may be reclassified subsequently to profit or loss		
Foreign currency translation adjustments	(4,642)	1,629
Other comprehensive income	(5,710)	3,107
Total comprehensive income	1,613	12,022
Profit attributable to		
Owners of the company	7,323	8,920
Non-controlling interests	—	(5)
Net profit for the period	7,323	8,915
Total comprehensive income attributable to		
Owners of the company	1,613	12,011
Non-controlling interests	—	12
Total comprehensive income	1,613	12,022
Earnings per share		
Basic earnings per share (yen)	17.68	21.96
Diluted earnings per share (yen)	17.61	21.88

Core basis (JPY millions)

	Three months ended June 30, 2016	Three months ended June 30, 2017
Revenue	50,006	55,949
Core operating profit	12,353	13,698
Core net profit for the period	8,762	9,991
Basic core earnings per share (yen)	21.15	24.61
Diluted core earnings per share (yen)	21.07	24.52
Core profit attributable to		
Owners of the company	8,762	9,996
Non-controlling interests	—	(5)
Core net profit for the period	8,762	9,991

Quarterly consolidated statement of financial position

Assets	(JPY millions)	
	March 31, 2017	June 30, 2017
Non-current assets		
Property, plant and equipment	28,550	28,602
Intangible assets	102,807	101,974
Financial assets	29,889	31,791
Deferred tax assets	2,396	2,204
Other non-current assets	2,124	2,255
Total non-current assets	165,767	166,825
Current assets		
Inventories	28,502	27,032
Trade and other receivables	70,970	77,079
Other financial assets	333	726
Other current assets	3,909	4,964
Cash and cash equivalents	53,297	48,952
Total current assets	157,011	158,752
Total assets	322,778	325,577

Equity and liabilities

(JPY millions)

	March 31, 2017	June 30, 2017
Equity		
Share capital	7,792	7,798
Capital surplus	8,417	8,423
Treasury shares	(10)	(10)
Retained earnings	223,418	227,059
Other components of equity	13,448	16,535
Total equity attributable to owners of the company	253,065	259,805
Non-controlling interests	819	831
Total equity	253,884	260,636
Liabilities		
Non-current liabilities		
Financial liabilities	7,619	6,160
Net defined benefit liabilities	1,900	2,078
Provisions	1,426	1,482
Deferred tax liabilities	2,596	3,583
Other non-current liabilities	1,919	1,352
Total non-current liabilities	15,460	14,654
Current liabilities		
Trade and other payables	23,937	23,728
Other financial liabilities	17,603	14,746
Income tax payable	3,279	3,245
Provisions	1,372	1,492
Other current liabilities	7,244	7,075
Total current liabilities	53,434	50,287
Total liabilities	68,894	64,941
Total equity and liabilities	322,778	325,577

Quarterly consolidated statement of changes in equity

Three months ended June 30, 2016

(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, 2016	7,695	8,389	(24)	221,945	—	18,676
Comprehensive income						
Net profit for the period				7,323		
Other comprehensive income						(1,067)
Total comprehensive income	—	—	—	7,323	—	(1,067)
Transactions with owners						
Issuance of new shares	12	12				
Acquisition of treasury shares			(0)			
Dividends				(5,384)		
Total transactions with owners	12	12	(0)	(5,384)	—	—
Balance at June 30, 2016	7,707	8,401	(24)	223,884	—	17,609

(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, 2016	2,611	716	22,003	260,009	—	260,009
Comprehensive income						
Net profit for the period			—	7,323		7,323
Other comprehensive income	(4,642)		(5,710)	(5,710)		(5,710)
Total comprehensive income	(4,642)	—	(5,710)	1,613	—	1,613
Transactions with owners						
Issuance of new shares		(8)	(8)	16		16
Acquisition of treasury shares			—	(0)		(0)
Dividends			—	(5,384)		(5,384)
Total transactions with owners	—	(8)	(8)	(5,369)	—	(5,369)
Balance at June 30, 2016	(2,031)	708	16,286	256,254	—	256,254

Three months ended June 30, 2017

(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)	223,418	—	9,470
Comprehensive income						
Net profit for the period				8,920		
Other comprehensive income						1,478
Total comprehensive income	—	—	—	8,920	—	1,478
Transactions with owners						
Issuance of new shares	6	6				
Acquisition of treasury shares			(0)			
Dividends				(5,280)		
Other				1		(1)
Total transactions with owners	6	6	(0)	(5,279)	—	(1)
Balance at June 30, 2017	7,798	8,423	(10)	227,059	—	10,947

(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, 2017	3,153	825	13,448	253,065	819	253,884
Comprehensive income						
Net profit for the period			—	8,920	(5)	8,915
Other comprehensive income	1,612		3,090	3,090	17	3,107
Total comprehensive income	1,612	—	3,090	12,011	12	12,022
Transactions with owners						
Issuance of new shares		(3)	(3)	10		10
Acquisition of treasury shares			—	(0)		(0)
Dividends			—	(5,280)		(5,280)
Other			(1)	—		—
Total transactions with owners	—	(3)	(4)	(5,271)	—	(5,271)
Balance at June 30, 2017	4,765	823	16,535	259,805	831	260,636

Quarterly consolidated statements of cash flows

(JPY millions)

	Three months ended June 30, 2016	Three months ended June 30, 2017
I . Cash flows from operating activities:		
Net profit for the period	7,323	8,915
Depreciation and amortization	2,396	2,666
Impairment losses	12	37
Finance income and expenses	(271)	(288)
Income tax expenses	2,930	3,294
Decrease (increase) in trade and other receivables	(4,033)	(5,659)
Decrease (increase) in inventories	(1,471)	1,905
Increase (decrease) in trade and other payables	(3)	(272)
Increase (decrease) in provisions and net defined benefit liabilities	(93)	237
Other	(1,282)	(3,267)
Subtotal	5,507	7,567
Interest received	13	20
Dividends received	266	274
Interest paid	(16)	(9)
Income tax paid	(20,032)	(2,777)
Net cash flows from (used in) operating activities	(14,262)	5,075
II . Cash flows from investing activities:		
Payments for acquisition of investments	(111)	(2)
Proceeds from sales of investments	—	2
Payments for acquisition of property, plant and equipment	(1,601)	(667)
Proceeds from sales of property, plant and equipment	2	—
Payments for acquisition of intangible assets	(2,392)	(516)
Other	(8)	(7)
Net cash flows from (used in) investing activities	(4,111)	(1,190)
III . Cash flows from financing activities:		
Proceeds from long-term loans	3,000	—
Repayments of long-term loans	(2,412)	(2,287)
Dividends paid	(5,279)	(5,181)
Other	19	9
Net cash flows from (used in) financing activities	(4,672)	(7,460)
IV . Net increase (decrease) in cash and cash equivalents	(23,044)	(3,576)
V . Cash and cash equivalents at the beginning of period	99,798	52,282
VI . Effect of exchange rate changes on cash and cash equivalents	(2,237)	245
VII . Cash and cash equivalents at the end of period	74,516	48,952

Segment information

Three months ended June 30, 2016

(JPY millions)

	<Reportable segment> Pharmaceuticals	Other (Note:1)	Total	Adjustments	Consolidated total
Revenue:					
External customers	49,258	748	50,006	—	50,006
Intersegment	—	141	141	(141)	—
Total	49,258	890	50,147	(141)	50,006
Segment income (loss) (Note:2)	10,843	(32)	10,811	—	10,811
				Finance income	427
				Finance expenses	(985)
				Profit before tax	10,253

Notes:1."Other" comprises operating segments other than the reportable segment, including the medical device operating segments.

2.Segment income (loss) is based on operating profit.

Three months ended June 30, 2017

(JPY millions)

	<Reportable segment> Pharmaceuticals	Other (Note:1)	Total	Adjustments	Consolidated total
Revenue:					
External customers	55,220	728	55,949	—	55,949
Intersegment	—	186	186	(186)	—
Total	55,220	914	56,135	(186)	55,949
Segment income (loss) (Note:2)	12,285	(229)	12,056	—	12,056
				Finance income	451
				Finance expenses	(298)
				Profit before tax	12,209

Notes:1."Other" comprises operating segments other than the reportable segment, including the medical device operating segments.

2.Segment income (loss) is based on operating profit.

Breakdown of revenues

Three months ended June 30, 2016

(JPY millions)

Pharmaceuticals business			Other businesses		Total
Prescription pharmaceuticals		OTC pharmaceuticals	Medical devices	Others	
Ophthalmics	Other pharmaceuticals				
45,722	568	2,967	620	129	50,006

Three months ended June 30, 2017

(JPY millions)

Pharmaceuticals business			Other businesses		Total
Prescription pharmaceuticals		OTC pharmaceuticals	Medical devices	Others	
Ophthalmics	Other pharmaceuticals				
50,923	317	3,980	608	120	55,949

Revenue of major pharmaceuticals

(JPY millions)

Brand name Generic name/formulation	Therapeutic category	Region	Year ended March 31, 2017				Year ending March 31, 2018			
			Three months ended June 30, 2016 Actual	Changes from same period of previous year	Year ended March 31 Actual	Changes from same period of previous year	Three months ended June 30, 2017 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	3,459	(15.4%)	12,884	(9.6%)	3,746	8.3%	13,945	8.2%
		Japan	1,334	(17.2%)	4,660	(21.3%)	1,175	(12.0%)	4,308	(7.5%)
		Asia	1,840	(12.1%)	6,980	(0.3%)	2,159	17.4%	8,252	18.2%
		Europe	285	(25.6%)	1,245	(6.5%)	412	44.4%	1,384	11.2%
Tarivid ofloxacin/ophthalmic solution	Bacterial conjunctivitis	Total	424	(31.6%)	1,541	(12.5%)	473	11.8%	1,455	(5.6%)
		Japan	157	(15.5%)	559	(16.9%)	144	(8.0%)	472	(15.6%)
		Asia	267	(38.5%)	982	(9.8%)	329	23.4%	983	0.1%
		Europe	—	—	—	—	—	—	—	—
Tapcom tafluprost-timolol maleate/ combination ophthalmic solution	Glaucoma	Total	632	106.0%	2,798	82.4%	925	46.4%	3,800	35.8%
		Japan	560	117.2%	2,256	63.4%	646	15.4%	2,587	14.6%
		Asia	5	—	38	—	26	417.8%	90	137.1%
		Europe	67	36.5%	504	229.3%	252	278.4%	1,124	122.9%
Tapros tafluprost/ophthalmic solution	Glaucoma	Total	4,151	12.3%	16,406	4.9%	4,521	8.9%	18,115	10.4%
		Japan	2,524	10.2%	9,592	4.6%	2,524	0.0%	10,489	9.3%
		Asia	313	17.3%	1,227	11.8%	411	31.4%	1,613	31.5%
		Europe	1,314	15.4%	5,587	4.1%	1,586	20.6%	5,985	7.1%
		Other	—	—	—	—	—	—	28	—
		Other	—	—	—	—	—	—	—	—
Cosopt dorzolamide hydrochloride-timolol maleate/combination ophthalmic solution	Glaucoma	Total	5,943	27.4%	22,164	7.7%	6,152	3.5%	23,013	3.8%
		Japan	3,054	7.7%	11,366	1.4%	3,004	(1.6%)	11,468	0.9%
		Asia	704	5.7%	2,669	7.1%	796	13.1%	2,913	9.1%
		Europe	2,185	87.6%	8,122	18.1%	2,352	7.7%	8,476	4.4%
		Other	—	—	6	—	—	—	156	—
Timoptol timolol maleate/ ophthalmic solution	Glaucoma	Total	453	(6.1%)	1,509	(21.8%)	402	(11.3%)	1,430	(5.2%)
		Japan	281	(15.2%)	967	(18.1%)	231	(17.5%)	853	(11.8%)
		Asia	31	(15.8%)	119	(14.8%)	28	(7.4%)	182	52.3%
		Europe	142	23.3%	422	(30.6%)	142	0.1%	395	(6.2%)
Timoptol XE timolol maleate/ long-acting ophthalmic solution	Glaucoma	Total	618	(4.8%)	2,382	(3.3%)	602	(2.6%)	2,179	(8.5%)
		Japan	459	(10.0%)	1,614	(14.4%)	392	(14.7%)	1,450	(10.2%)
		Asia	23	1.3%	88	0.8%	26	14.0%	42	(52.4%)
		Europe	136	16.7%	679	38.8%	184	35.4%	687	1.1%
Trusopt dorzolamide hydrochloride/ ophthalmic solution	Glaucoma	Total	1,135	9.1%	4,343	(4.8%)	1,189	4.8%	3,906	(10.1%)
		Japan	477	(17.3%)	1,731	(18.6%)	448	(6.1%)	1,396	(19.3%)
		Asia	69	(52.1%)	271	(39.3%)	78	12.9%	280	3.3%
		Europe	588	84.5%	2,333	17.2%	662	12.4%	2,194	(6.0%)
		Other	—	—	9	—	2	—	36	298.4%
Rescula isopropyl unoprostone/ ophthalmic solution	Glaucoma	Total	458	(5.7%)	1,633	(11.5%)	403	(12.0%)	1,641	0.5%
		Japan	458	(5.7%)	1,633	(11.5%)	403	(12.0%)	1,641	0.5%
Alesion epinastine hydrochloride/ ophthalmic solution	Allergy	Total	2,034	72.0%	12,235	29.0%	2,666	31.1%	14,926	22.0%
		Japan	2,034	72.0%	12,235	29.0%	2,666	31.1%	14,926	22.0%
Flumetholon fluorometholone/ ophthalmic solution	Inflammation	Total	860	(7.1%)	3,347	(11.3%)	901	4.8%	3,425	2.3%
		Japan	561	(9.1%)	2,224	(16.2%)	544	(3.1%)	2,123	(4.5%)
		Asia	299	(3.2%)	1,123	0.3%	358	19.5%	1,302	15.9%
Kary Uni pirenoxine/ ophthalmic solution	Senile cataract	Total	1,057	(3.9%)	4,124	(1.5%)	1,222	15.7%	4,439	7.7%
		Japan	766	3.7%	2,833	(2.3%)	734	(4.2%)	2,776	(2.0%)
		Asia	291	(19.4%)	1,291	0.3%	489	68.2%	1,663	28.8%
Opegan Hi sodium hyaluronate/ adjuvant for ophthalmic operations	Adjuvant for ophthalmic operations	Total	630	(5.6%)	2,285	(11.0%)	621	(1.5%)	2,288	0.1%
		Japan	630	(5.6%)	2,285	(11.0%)	621	(1.5%)	2,288	0.1%
Eylea afibercept/ solution for intravitreal injection	Intravitreal VEGF inhibitor	Total	11,894	32.1%	45,155	12.9%	13,107	10.2%	46,199	2.3%
		Japan	11,894	32.1%	45,155	12.9%	13,107	10.2%	46,199	2.3%
Hyalein sodium hyaluronate/ophthalmic solution	Dry eye	Total	4,763	(7.6%)	17,595	(11.4%)	4,709	(1.1%)	17,483	(0.6%)
		Japan	3,267	(14.0%)	11,852	(18.2%)	2,993	(8.4%)	10,743	(9.4%)
		Asia	1,496	10.1%	5,743	6.9%	1,717	14.7%	6,740	17.4%
Diquas diquafosol sodium/ophthalmic solution	Dry eye	Total	2,918	29.1%	11,940	24.0%	3,511	20.3%	14,574	22.1%
		Japan	2,684	28.7%	11,016	24.1%	3,189	18.8%	12,642	14.8%
		Asia	234	34.5%	924	23.1%	322	37.7%	1,932	109.0%
Ikervis ciclosporin/ophthalmic solution	Dry eye	Total	164	—	1,303	73.5%	479	191.8%	2,344	79.9%
		Asia	—	—	2	—	2	—	64	—
		Europe	164	—	1,301	73.2%	478	190.9%	2,226	71.1%
		North America	—	—	—	—	—	—	49	—
		Other	—	—	—	—	—	—	6	—
		Other	—	—	—	—	—	—	—	—
Cationorm	Dry eye	Total	321	34.2%	1,835	26.3%	503	56.6%	2,587	41.0%
		Asia	28	19.3%	206	23.4%	62	118.0%	344	67.0%
		Europe	291	34.8%	1,318	28.1%	389	33.6%	1,894	43.7%
		North America	—	—	280	15.7%	51	—	287	2.4%
		Other	2	—	31	114.9%	2	(5.2%)	62	101.7%
OTC pharmaceuticals			2,967	24.4%	12,553	14.1%	3,980	34.1%	12,900	2.8%

Exchange rate (yen)	Major currency	1st quarter ended June 30, 2016	Fiscal year ended March 31, 2017	1st quarter ended June 30, 2017	Fiscal year to March 31, 2018(Forecasts)
	US dollar	108.83	108.64	111.33	110.00
Euro	122.53	118.96	122.95	120.00	
RMB	16.63	16.14	16.22	16.50	

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

Research & development

As of August 1, 2017

■ 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				Jan-2012		
<p>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. NDA filed in China in January 2012. Launched in October 2013 in Korea. Launched in Vietnam in February 2016. Launched in Thailand in April 2016. Currently seeking sequential approvals for marketing in Asia.</p>										

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
sirolimus	DE-109	Uveitis	Original	U.S.				Feb-2017		
				Japan						
				Europe						
				Asia				Apr-2015		
<p>An intravitreal injection with immunosuppressive effect, anti-angiogenic effect, etc. NDA filed in the U.S. in February 2017. Preparing NDA file in Europe. NDA filed in Asia in April 2015.</p>										

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
epinastine hydrochloride	DE-114A	Allergic conjunctivitis	Nippon Boehringer Ingelheim	Japan						
<p>An H₁ receptor antagonist with membrane-stabilizing function, as treatment for allergic conjunctivitis. High dose drug. Started Phase 3 in Japan in May 2017.</p>										

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
omidenedapag isopropyl	DE-117	Glaucoma/ Ocular hypertension	Co-development with Ube Industries	U.S.						
				Japan			(Phase 2b/3)			
				Asia						
<p>An EP2 receptor agonist with a new mechanism of action. Completed Phase 2b in the U.S. in February 2015. Started Phase 2b/3 in Japan in December 2015. Started Phase 3 in Asia in December 2016.</p>										

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
carotuximab	DE-122	Wet Age-related macular degeneration	TRACON Pharmaceuticals	U.S.		(Phase 2a)				
<p>An intravitreal injection of anti-endothelin antibody. Started Phase 1/2 in the U.S. in September 2015 and started Phase 2a in July 2017.</p>										

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
sepetaprost	DE-126	Glaucoma/ Ocular hypertension	ONO PHARMACEUTICAL	U.S.		(Phase 2b)				
				Japan		(Phase 2b)				
<p>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 the U.S. and Japan in July 2017.</p>										

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
—	DE-128 <i>(InnFocus MicroShunt)</i>	Glaucoma	Original	U.S.			(Phase 2/3)			
—				Europe						
<p>In August 2016, acquired InnFocus, developer of <i>InnFocus MicroShunt</i>. MicroShunt is 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.</p>										

Generic name	Dev. name	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
ciclosporin	Cyclokot	Severe keratitis in patients with dry eye	Original	U.S.						
				Asia				Nov-2016		
				Others				Apr-2016		
<p>An ophthalmic emulsion to treat severe keratitis in adult patients with dry eye through an immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue absorption. Launched in Germany and England in July 2015 and planning successive launches in European countries. NDA filed in Asian countries successively and approved in some countries including Thailand (November 2016) and Korea (March 2017). NDA filed in Canada in April 2016.</p>										

Generic name	Dev. name	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
ciclosporin	Vekacia	Vernal Keratoconjunctivitis	Original	Europe				Dec-2016		
<p>An ophthalmic emulsion which improves vernal keratoconjunctivitis by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue absorption. NDA filed and granted Priority Review status in Europe in December 2016. In July 2017, the Committee for Human Medicinal Products of the European Medicines Agency adopted a positive opinion, recommending the marketing authorization.</p>										

Generic name	Dev. name	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
latanoprost	Catioprost	Glaucoma/ Ocular hypertension	Original	Europe						
An ophthalmic emulsion of a prostaglandin F _{2α} derivative, for the treatment of glaucoma and ocular hypertension.										

■ Changes from Q4 FY16 (May 10, 2017)

Dev. code / name	Changes
DE-114A	Started Phase 3 in Japan in May 2017.

Other consolidated information

Capital expenditures

(JPY millions)

	Three months ended June 30, 2016	Year ended March 31, 2017	Three months ended June 30, 2017	Year ending March 31, 2018
	Actual			Forecast
Consolidated	1,555	5,216	974	7,660

Depreciation and amortization

(JPY millions)

	Three months ended June 30, 2016	Year ended March 31, 2017	Three months ended June 30, 2017	Year ending March 31, 2018
	Actual			Forecast
Manufacturing cost	368	1,515	470	1,880
Selling, general and administrative expenses	281	1,246	357	1,270
R&D expenses	161	709	184	680
Consolidated total	810	3,470	1,011	3,830

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, 2016	Year ended March 31, 2017	Three months ended June 30, 2017	Year ending March 31, 2018
	Actual			Forecast
Intangible assets (Merck products)	1,318	5,357	1,380	5,590
Intangible assets (Ikervis)	174	674	174	680
Other	94	381	102	350
Consolidated total	1,586	6,412	1,656	6,620

Research and Development expenses

(JPY millions)

	Three months ended June 30, 2016	Year ended March 31, 2017	Three months ended June 30, 2017	Year ending March 31, 2018
	Actual			Forecast
Consolidated	5,158	22,786	5,613	25,000
Percent of revenue	10.3%	11.4%	10.0%	11.5%

*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.