

Santen Consolidated Results for Q2 Fiscal 2016

November 2, 2016 – Santen Pharmaceutical Co., Ltd. (Osaka, JAPAN, Tokyo Stock Exchange Code 4536) (Santen) today announced consolidated performance for Q2 FY16, the cumulative six month period ended September 30, 2016.

Boosted by the sales of new products, Santen's results included year-on-year revenue growth in Japan of 2% (8% growth excluding revenue in the prior year from the anti-rheumatoid business sold in 2015). Overseas revenue was lower due to the impact of the Japanese yen appreciation against other currencies. However, on a local currency basis, revenue in areas including EMEA (Europe, the Middle East and Africa) and China grew briskly by 27% and 15%, respectively. Core net profit for the period increased 2% compared to the prior year. Santen maintains its forecasts for the full year ending March 31, 2017. As a special shareholder return initiative, Santen announced the repurchase of its own shares in an amount up to 13 billion yen on September 12, 2016.

Core basis*	Q2 FY16** actual (million yen)	change (YoY%)	FY16 forecast (million yen)	change (YoY%)
Revenue	97,829	-0.0%	200,000	+2.4%
Core operating profit	22,464	-8.5%	44,100	+2.3%
Core net profit for the period	16,712	+2.0%	30,200	+3.5%
Earnings per share (basic)	¥ 40.37		¥ 72.92	

IFRS basis	Q2 FY16** actual (million yen)	change (YoY%)	FY16 forecast (million yen)	change (YoY%)
Revenue	97,829	-0.0%	200,000	+2.4%
Operating profit	18,787	-71.3%	36,300	-54.7%
Net profit for the period	12,601	-71.1%	25,300	-52.6%

* Core basis results are non-IFRS measures that remove 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. A gain of 45 billion yen related the company's sale of its anti-rheumatic business in August 2015 is included in FY15 operating profit on an IFRS basis but excluded from core basis results.

** Santen results herein describe Q2 results cumulatively as the six month period ended September 30, 2016
Additional Santen investor relations information can be found here: <http://www.santen.com/en/ir/>.

About Santen

As a specialty company dedicated to the ophthalmic field, Santen carries out research, development, marketing and sales of pharmaceuticals. Santen is the market leader in Japan for prescription ophthalmic pharmaceuticals and sells products in over 50 countries. As a leading company in the field of ophthalmology, Santen aims to contribute to society by supplying valuable products and services to satisfy unmet medical needs. For more details, please see 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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Disclaimer: The following is meant to be an accurate translation from the original Financial Report of Santen Pharmaceutical Co., Ltd., written in Japanese, and is prepared for the information disclosure to the Tokyo Stock Exchange. However, in the case of any discrepancy between the English translation and the Japanese original, the latter shall prevail.

(Millions of yen)

1. Consolidated performance for the six months ended September 30, 2016

(1) Operating results

	Six months ended September 30, 2015	Six months ended September 30, 2016	% change
Revenue	97,873	97,829	(0.0%)
Operating profit	65,385	18,787	(71.3%)
Profit before tax	65,335	17,027	(73.9%)
Net profit for the period	43,657	12,601	(71.1%)
Net profit for the period attributable to owners of the company	43,657	12,601	(71.1%)
Total comprehensive income for the period	43,507	2,339	(94.6%)
Basic earnings per share (yen)	105.55	30.44	
Diluted earnings per share (yen)	105.06	30.32	

(Core basis *1)

	Six months ended September 30, 2015	Six months ended September 30, 2016	% change
Revenue	97,873	97,829	(0.0%)
Core operating profit	24,541	22,464	(8.5%)
Core net profit for the period	16,392	16,712	+2.0%
Basic core earnings per share (yen)	39.63	40.37	
Diluted core earnings per share (yen)	39.45	40.22	

(2) Financial position

	March 31, 2016	September 30, 2016
Total assets	355,399	323,555
Total equity	260,009	255,065
Total equity attributable to owners of the company	260,009	255,065
Total equity attributable to owners of the company ratio	73.2%	78.8%
Equity per share attributable to owners of the company (yen)	627.78	617.90

2. Dividends

	Year to March 2016	Year to March 2017	(Forecasts) Year to March 2017
First quarter dividends per share (yen)	—	—	
Second quarter dividends per share (yen)	12.00	13.00	
Third quarter dividends per share (yen)	—		—
Year-end dividends per share (yen)	13.00		13.00
Annual dividends per share (yen)	25.00		26.00

3. Consolidated forecasts of results for the year ending March 31, 2017

	Year to March 2017	% change
Revenue	200,000	+2.4%
Operating profit	36,300	(54.7%)
Profit before tax	36,500	(54.1%)
Net profit for the year	25,300	(52.6%)
Net profit for the year attributable to owners of the company	25,300	(52.6%)
Basic earnings per share (yen)	61.09	

(Core basis *1)

	Year to March 2017	% change
Revenue	200,000	+2.4%
Core operating profit	44,100	+2.3%
Core net profit for the year	30,200	+3.5%
Core earnings per share (yen)	72.92	

*Others

(1) Changes in significant subsidiaries during the term (changes in designated subsidiaries resulting in adjustment to the scope of consolidation): Yes

Increase: 1 subsidiary (subsidiary name: Chongqing Santen Kerui Pharmaceutical Co., Ltd.)

Note: 4 companies, Santen Business Services Co., Ltd. Santen Eye Care Co., Ltd., Santen Pharmaceutical (Hong Kong) Limited., and InnFocus, Inc., have newly become our consolidated subsidiaries.

(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)

September 30, 2016: 414,251,515

March 31, 2016 : 414,191,515

[ii] Number of treasury shares at the end of period

September 30, 2016: 1,454,571

March 31, 2016 : 22,369

[iii] Average number of outstanding shares (during the fiscal year ended September 30)

Second quarter ended September 30, 2016: 413,976,129

Second quarter ended September 30, 2015: 413,596,490

(Information regarding the implementation of audit procedures)

These quarterly financial results are not subject to quarterly review procedures. Thus, at the time of disclosure of these financial results, the quarterly consolidated financial statement review procedures based on the Financial Instruments and Exchange Law, are in progress.

(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		(Millions of yen)
	Six months ended September 30, 2015	Six months ended September 30, 2016
Revenue	97,873	97,829
Cost of sales	(36,501)	(36,836)
Gross profit	61,372	60,993
Selling, general and administrative expenses	(27,588)	(28,738)
Research and development expenses	(9,243)	(10,304)
Amortization on intangible assets associated with products	(2,999)	(3,169)
Other income	44,705	216
Other expenses	(861)	(211)
Operating profit	65,385	18,787
Finance income	450	445
Finance expenses	(500)	(2,206)
Profit before tax	65,335	17,027
Income tax expenses	(21,679)	(4,426)
Net profit for the period	43,657	12,601
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	(263)	(5,456)
Items that may be reclassified subsequently to profit or loss		
Foreign currency translation adjustments	112	(4,806)
Other comprehensive income	(150)	(10,262)
Total comprehensive income	43,507	2,339
Earnings per share		
Basic earnings per share (yen)	105.55	30.44
Diluted earnings per share (yen)	105.06	30.32

Core basis		(Millions of yen)
	Six months ended September 30, 2015	Six months ended September 30, 2016
Revenue	97,873	97,829
Core operating profit	24,541	22,464
Core net profit for the period	16,392	16,712
Basic core earnings per share (yen)	39.63	40.37
Diluted core earnings per share (yen)	39.45	40.22

Quarterly consolidated statement of financial position

Assets		(Millions of yen)
	March 31, 2016	September 30, 2016
Non-current assets		
Property, plant and equipment	27,991	28,521
Intangible assets	83,681	100,543
Financial assets	44,535	34,152
Deferred tax assets	2,345	1,947
Other non-current assets	2,109	1,765
Total non-current assets	160,660	166,928
Current assets		
Inventories	24,996	26,784
Trade and other receivables	65,998	66,687
Other financial assets	234	187
Other current assets	3,714	4,626
Cash and cash equivalents	99,798	58,343
Total current assets	194,739	156,626
Total assets	355,399	323,555

Equity and liabilities		(Millions of yen)
	March 31, 2016	September 30, 2016
Equity		
Share capital	7,695	7,716
Capital surplus	8,389	8,402
Treasury shares	(24)	(2,089)
Retained earnings	221,945	230,217
Other components of equity	22,003	10,819
Total equity attributable to owners of the company	260,009	255,065
Total equity	260,009	255,065
Liabilities		
Non-current liabilities		
Financial liabilities	12,944	11,361
Net defined benefit liabilities	2,556	2,450
Provisions	1,629	1,420
Deferred tax liabilities	3,988	2,004
Other non-current liabilities	1,043	933
Total non-current liabilities	22,161	18,168
Current liabilities		
Trade and other payables	24,504	23,745
Other financial liabilities	19,881	15,598
Income tax payable	20,431	3,414
Provisions	1,276	1,239
Other current liabilities	7,138	6,326
Total current liabilities	73,230	50,322
Total liabilities	95,391	68,489
Total equity and liabilities	355,399	323,555

Quarterly consolidated statement of changes in equity

Six months ended September 30, 2015

	(Millions of yen)					
	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, 2015	7,383	8,077	(18)	178,840	—	11,944
Comprehensive income						
Net profit for the period				43,657		
Other comprehensive income						(263)
Total comprehensive income	—	—	—	43,657	—	(263)
Transactions with owners						
Issuance of new shares	190	190				
Acquisition of treasury shares			(5)			
Dividends				(4,959)		
Share-based payments						
Other				414		(414)
Total transactions with owners	190	190	(5)	(4,545)	—	(414)
Balance at September 30, 2015	7,573	8,268	(24)	217,952	—	11,268

	(Millions of yen)				
	Other components of equity			Total equity attributable to owners of the company	Total equity
	Foreign currency translation adjustments	Subscription rights to shares	Total		
Balance at April 1, 2015	5,000	553	17,497	211,779	211,779
Comprehensive income					
Net profit for the period			—	43,657	43,657
Other comprehensive income	112		(150)	(150)	(150)
Total comprehensive income	112	—	(150)	43,507	43,507
Transactions with owners					
Issuance of new shares		(53)	(53)	328	328
Acquisition of treasury shares			—	(5)	(5)
Dividends			—	(4,959)	(4,959)
Share-based payments		249	249	249	249
Other			(414)	—	—
Total transactions with owners	—	197	(217)	(4,387)	(4,387)
Balance at September 30, 2015	5,113	749	17,130	250,899	250,899

Six months ended September 30, 2016

	(Millions of yen)					
	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				12,601		
Other comprehensive income						(5,456)
Total comprehensive income	—	—	—	12,601	—	(5,456)
Transactions with owners						
Issuance of new shares	21	21				
Acquisition of treasury shares		(8)	(2065)			
Disposal of treasury shares			0			
Dividends				(5,384)		
Share-based payments						
Other				1,056		(1,051)
Total transactions with owners	21	13	(2,065)	(4,329)	—	(1,051)
Balance at September 30, 2016	7,716	8,402	(2,089)	230,217	—	12,169

	(Millions of yen)				
	Other components of equity			Total equity attributable to owners of the company	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			—	12,601	12,601
Other comprehensive income	(4,806)		(10,262)	(10,262)	(10,262)
Total comprehensive income	(4,806)	—	(10,262)	2,339	2,339
Transactions with owners					
Issuance of new shares		(6)	(6)	36	36
Acquisition of treasury shares			—	(2,073)	(2,073)
Disposal of treasury shares			—	0	0
Dividends			—	(5,384)	(5,384)
Share-based payments		138	138	138	138
Other		(4)	(1,056)	—	—
Total transactions with owners	—	128	(923)	(7,282)	(7,282)
Balance at September 30, 2016	(2,195)	844	10,819	255,065	255,065

Quarterly consolidated statements of cash flows

	(Millions of yen)	
	Six months ended September 30, 2015	Six months ended September 30, 2016
I. Cash flows from operating activities:		
Net profit for the period	43,657	12,601
Depreciation and amortization	4,511	4,837
Impairment losses	313	67
Finance income and expenses	(261)	1,611
Income tax expenses	21,679	4,426
Gain on disposal of disposal groups	(44,477)	—
Decrease (increase) in trade and other receivables	(3,943)	(1,751)
Decrease (increase) in inventories	(1,915)	(2,879)
Increase (decrease) in trade and other payables	2,627	(501)
Increase (decrease) in provisions and net defined benefit liabilities	163	(83)
Other	(3,264)	(3,167)
Subtotal	19,090	15,160
Interest received	28	33
Dividends received	281	268
Interest paid	(49)	(30)
Income tax paid	(6,965)	(20,480)
Net cash flows from (used in) operating activities	12,385	(5,049)
II. Cash flows from investing activities:		
Payments into time deposits	(22)	—
Proceeds from withdrawal of time deposits	22	19
Payments for acquisition of investments	(1,963)	(114)
Proceeds from sale and redemption of investments	1,310	483
Acquisition of shares of subsidiaries	—	(19,047)
Payments for acquisition of property, plant and equipment	(2,588)	(2,066)
Proceeds from sales of property, plant and equipment	32	4
Payments for acquisition of intangible assets	(1,261)	(2,751)
Proceeds on disposal of disposal groups	45,000	—
Other	(18)	(233)
Net cash flows from (used in) investing activities	40,512	(23,705)
III. Cash flows from financing activities:		
Proceeds from long-term loans	—	3,000
Repayments of long-term loans	(5,897)	(4,825)
Acquisition of treasury shares	(5)	(2,073)
Dividends paid	(4,954)	(5,385)
Other	327	43
Net cash flows from (used in) financing activities	(10,529)	(9,239)
IV. Net increase (decrease) in cash and cash equivalents	42,368	(37,993)
V. Cash and cash equivalents at the beginning of period	65,923	99,798
VI. Effect of exchange rate changes on cash and cash equivalents	(280)	(3,462)
VII. Cash and cash equivalents at the end of period	108,011	58,343

Segment information

Six months ended September 30, 2015

(Millions of yen)

	<Reportable segment> Pharmaceuticals	Other (Note: 1)	Total	Adjustments	Consolidated total
Revenue:					
External customers	96,540	1,334	97,873	—	97,873
Intersegment	—	329	329	(329)	—
Total	96,540	1,663	98,202	(329)	97,873
Segment income(loss)					
(Note: 2)	66,003	(618)	65,385	—	65,385
				Finance income	450
				Finance expenses	(500)
				Profit before tax	65,335

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.

Six months ended September 30, 2016

(Millions of yen)

	<Reportable segment> Pharmaceuticals	Other (Note: 1)	Total	Adjustments	Consolidated total
Revenue:					
External customers	96,302	1,528	97,829	—	97,829
Intersegment	—	281	281	(281)	—
Total	96,302	1,809	98,111	(281)	97,829
Segment income(loss)					
(Note: 2)	19,013	(226)	18,787	—	18,787
				Finance income	445
				Finance expenses	(2,206)
				Profit before tax	17,027

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.

3. The assets of the "Pharmaceuticals" largely increase in comparison with a previous consolidated account end of the fiscal year by acquiring total stocks of InnFocus, Inc., and having subsidized it.

Breakdown of revenues

Six months ended September 30, 2015

(Millions of yen)

Pharmaceuticals business				Other businesses		Total
Prescription pharmaceuticals			OTC pharma- ceuticals	Medical devices	Others	
Ophthalmics	Anti- rheumatics	Other pharma- ceuticals				
84.521	3.514	3.599	4.906	1.179	154	97.873

Six months ended September 30, 2016

(Millions of yen)

Pharmaceuticals business				Other businesses		Total
Prescription pharmaceuticals			OTC pharma- ceuticals	Medical devices	Others	
Ophthalmics	Anti- rheumatics	Other pharma- ceuticals				
89.251	—	965	6.087	1.272	256	97.829

Revenue of major prescription pharmaceuticals

(Millions of yen)

Brand name Generic name/formulation	Therapeutic category	Region	Year ended March 31, 2016				Year ending March 31, 2017			
			Six months ended September 30, 2015 Actual	Changes from same period of previous year	Year ended March 31 Actual	Changes from same period of previous year	Six months ended September 30, 2016 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	8,032	16.5%	14,250	6.4%	6,914	Δ13.9%	11,437	Δ19.7%
		Japan	3,280	Δ6.6%	5,918	Δ8.9%	2,601	Δ20.7%	4,439	Δ25.0%
		Asia	4,058	49.9%	7,001	29.1%	3,704	Δ8.7%	5,689	Δ18.7%
		Europe	694	2.9%	1,331	Δ10.0%	610	Δ12.2%	1,309	Δ1.6%
Tarivid ofloxacin/ophthalmic solution	Bacterial conjunctivitis	Total	1,086	13.0%	1,761	Δ7.8%	858	Δ21.0%	1,348	Δ23.5%
		Japan	374	Δ10.4%	673	Δ11.7%	312	Δ16.8%	422	Δ37.3%
		Asia	712	31.0%	1,088	Δ5.2%	547	Δ23.2%	926	Δ14.9%
		Total	637	-	1,534	302.3%	1,282	101.4%	2,283	48.8%
Tapcom tafluprost-timolol maleate/ combination ophthalmic solution	Glaucoma	Japan	561	-	1,381	303.3%	1,116	99.0%	1,734	25.6%
		Asia	-	-	-	-	12	-	7	-
		Europe	76	-	153	292.8%	155	103.1%	541	253.4%
		Total	7,729	32.4%	15,633	26.8%	8,186	5.9%	17,030	8.9%
Tapros tafluprost/ophthalmic solution	Glaucoma	Japan	4,613	18.2%	9,168	10.1%	4,961	7.5%	10,285	12.2%
		Asia	550	38.5%	1,097	34.3%	570	3.6%	1,251	14.0%
		Europe	2,566	67.0%	5,368	68.6%	2,654	3.5%	5,487	2.2%
		Other	-	-	-	-	-	-	7	-
Cosopt dorzolamide hydrochloride-timolol maleate/combination ophthalmic solution	Glaucoma	Total	9,804	86.6%	20,583	65.0%	11,176	14.0%	21,610	5.0%
		Japan	5,705	8.9%	11,214	4.9%	5,887	3.2%	11,719	4.5%
		Asia	1,269	-	2,493	179.6%	1,303	2.7%	2,381	Δ4.5%
		Europe	2,830	-	6,876	666.4%	3,986	40.9%	7,451	8.4%
Timoptol timolol maleate/ ophthalmic solution	Glaucoma	Other	-	-	-	-	-	-	59	-
		Total	1,032	88.3%	1,930	52.3%	845	Δ18.1%	1,414	Δ26.7%
		Japan	637	16.3%	1,182	Δ2.8%	522	Δ18.0%	902	Δ23.7%
		Asia	74	-	140	380.8%	63	Δ14.5%	118	Δ15.6%
Timoptol XE timolol maleate/ long-acting ophthalmic solution	Glaucoma	Europe	321	-	608	-	260	Δ19.1%	393	Δ35.3%
		Total	1,296	50.0%	2,463	24.1%	1,173	Δ9.5%	2,411	Δ2.1%
		Japan	998	15.6%	1,886	Δ1.6%	867	Δ13.1%	1,558	Δ17.4%
		Asia	45	-	87	221.9%	41	Δ8.0%	81	Δ6.9%
Trusopt dorzolamide hydrochloride/ ophthalmic solution	Glaucoma	Europe	253	-	489	-	265	4.7%	772	57.7%
		Total	2,193	469.0%	4,561	146.2%	2,159	Δ1.6%	3,647	Δ20.0%
		Japan	1,132	194.0%	2,125	37.6%	914	Δ19.2%	1,533	Δ27.9%
		Asia	296	-	446	706.0%	137	Δ53.8%	240	Δ46.1%
Detantol bunazosin hydrochloride/ ophthalmic solution	Glaucoma	Europe	765	-	1,990	688.7%	1,108	44.8%	1,863	Δ6.4%
		Other	-	-	-	-	-	-	11	-
		Japan	594	Δ2.9%	1,117	Δ9.1%	562	Δ5.3%	1,060	Δ5.1%
		Rescula isopropyl unoprostone/ ophthalmic solution	Glaucoma	Japan	967	Δ0.6%	1,845	Δ4.7%	870	Δ10.0%
Alesion epinastine hydrochloride/ ophthalmic solution	Allergy	Japan	2,745	75.6%	9,483	41.6%	4,066	48.2%	11,741	23.8%
Flumetholon fluorometholone/ ophthalmic solution	Inflammation	Total	2,015	3.5%	3,775	Δ0.9%	1,781	Δ11.6%	3,277	Δ13.2%
		Japan	1,287	Δ3.3%	2,655	Δ6.6%	1,104	Δ14.2%	2,219	Δ16.4%
		Asia	728	18.2%	1,120	15.8%	677	Δ7.0%	1,057	Δ5.6%
Kary Uni pirenoxine/ ophthalmic solution	Senile cataract	Total	2,268	13.8%	4,187	7.1%	2,120	Δ6.5%	4,051	Δ3.2%
		Japan	1,495	1.5%	2,900	Δ0.3%	1,502	0.4%	2,835	Δ2.2%
		Asia	773	48.8%	1,287	28.6%	618	Δ20.0%	1,216	Δ5.5%
Opegan Hi sodium hyaluronate/ adjuvant for ophthalmic operations	Adjuvant for ophthalmic operations	Japan	1,335	3.4%	2,568	Δ0.2%	1,187	Δ11.1%	2,318	Δ9.7%
Eylea aflibercept/ solution for intravitreal injection	Intravitreal VEGF inhibitor	Japan	19,575	84.2%	39,988	60.7%	22,820	16.6%	45,688	14.3%
Hyalein sodium hyaluronate/ophthalmic solution	Dry eye	Total	10,407	5.4%	19,864	1.3%	9,308	Δ10.6%	15,680	Δ21.1%
		Japan	7,576	Δ1.8%	14,491	Δ5.4%	6,256	Δ17.4%	10,457	Δ27.8%
		Asia	2,832	31.4%	5,372	25.1%	3,052	7.8%	5,223	Δ2.8%
Diquas diquafosol sodium/ophthalmic solution	Dry eye	Total	4,576	27.3%	9,631	22.0%	5,795	26.6%	13,357	38.7%
		Japan	4,232	24.8%	8,880	19.7%	5,403	27.7%	12,313	38.7%
		Asia	344	68.6%	751	57.7%	391	13.7%	1,043	38.9%
Ikervis cyclosporin/ophthalmic souldion	Dry eye	Europe	159	-	751	-	452	185.2%	1,922	155.8%
Cationorm	Dry eye	Total	536	104.7%	1,453	77.3%	755	40.9%	2,267	56.1%
		Asia	65	154.0%	167	89.6%	83	27.1%	258	54.6%
		Europe	427	111.3%	1,029	75.7%	619	44.9%	1,712	66.4%
		North America	41	29.9%	242	68.9%	44	8.1%	243	0.5%
		Other	2	Δ5.2%	14	493.7%	8	270.9%	53	268.9%
OTC pharmaceuticals			4,906	51.0%	11,004	64.1%	6,087	24.1%	13,849	25.9%

*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

■ Pipeline of prescription pharmaceuticals (Clinical Stage)

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
tafluprost	DE-085	Glaucoma/ Ocular hypertension	Co-development with Asahi Glass	China						Mar-16
A prostaglandin $F_{2\alpha}$ derivative for the treatment of glaucoma and ocular hypertension. Since December, 2008, launched in Japan, Europe, and the U.S. In Asia, launched in Hong Kong, Korea, Indonesia, and Singapore, etc. Launched in China in March 2016.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
diquafosol sodium	DE-089	Dry eye	Merck Sharp & Dohme Corp. (U.S.)	China				Jan-12		
				Asia						Feb-16
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 and in October 2013 in Korea. NDA filed in China in January 2012. Launched in Vietnam in February 2016. Launched in Thailand in April 2016. Currently seeking sequential approvals for marketing in Asia.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
lomerizine HCl	DE-090	Glaucoma	MSD K.K.	Japan						
A new type of glaucoma treatment which inhibits the progression of visual field defects. It is the only calcium antagonist being development as an oral glaucoma treatment. Compared to NMDA receptor antagonists, it has excellent safety profile with mild systemic adverse drug reactions.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
sirolimus	DE-109	Uveitis	Original	U.S.						
				Japan						
				Europe						
				Asia			Apr-15			
An intravitreal injection with immunosuppressive effect, anti-angiogenic effect, etc. Completed LPO (Last patient out) on Phase 3 study in the U.S. NDA filed in Asia in April 2015. Withdrew MAA file in May 2016 and plan to resubmit an application in Europe.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
tafluprost/ timolol maleate	DE-111	Glaucoma/ Ocular hypertension	Co-development with Asahi Glass	Korea						Apr-16
				Asia						Mar-16
A fixed dose combination drug of a prostaglandin $F_{2\alpha}$ derivative and a beta-adrenergic receptor blocker. Launched in Japan in November 2014. Approved successively in EU countries since October 2014 and launched since January 2015. Launched in Korea in April 2016. NDA being filed in Asian countries successively, and approved in Thailand, etc.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
omidenepag isopropyl	DE-117	Glaucoma/ Ocular hypertension	Co-development with Ube Industries	U.S.						
				Japan	(Phase 2b/3)					
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. Preparing Phase 3 in Korea and Asia.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
tafluprost	DE-118	Glaucoma/ Ocular hypertension	Co-development with Asahi Glass	Asia						Apr-16
A prostaglandin $F_{2\alpha}$ derivative for the treatment of glaucoma and ocular hypertension. Preservative-free, single dose type product. Launched in October 2013 in Japan. Acquired marketing approval in Hong Kong since June 2015. Seeking sequential approvals for marketing in Asian countries. Launched in Singapore and another county since April, 2016.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
TBD	DE-120	Wet Age-related macular degeneration	Original	U.S.						
An intravitreal injection with dual inhibitor of VEGF and PDGF. Started Phase 2a in the U.S. in April 2015.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
TBD	DE-122	Wet Age-related macular degeneration	TRACON Pharmaceuticals	U.S.		(Phase 1/2)				
An intravitreal injection of anti-endoglin antibody. Started Phase 1/2 in the U.S. in September 2015.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
sepetaprost	DE-126	Glaucoma/ Ocular hypertension	ONO PHARMACEUTICAL	U.S.	(Phase 2a)					
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. Preparing Phase 2b in U.S.										

Generic name	Dev. name	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
ciclosporin	Cyclokat	Severe keratitis in patients with dry eye	Original	Europe	Jul-15					
				U.S.						
				Korea	Dec-2015					
				Asia	Nov-2015					
An ophthalmic emulsion which improves severe keratitis in adult patients with dry eye by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue absorption. Luanchd in Germany and UK in July 2015 and planning successive launches in EU countries. NDA filed in Asian countries successively since November 2015 and in Korea in December 2015.										

Generic name	Dev. name	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
ciclosporin	Vekacia	Vernal Keratoconjunctivitis	Original	Europe						
An ophthalmic emulsion which improves vernal keratoconjunctivitis by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue absorption. Completed Phase3 in Europe in March 2016.										

Generic name	Dev. name	Indication	Original/Licensor	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.										

Generic name	Dev. name	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
dexamethasone palmitate	Cortiject	Diabetic macular edema	Original	Europe	(Phase 1/2)					
An intravitreal injection with anti-inflammatory effect.										

—	Dev. Code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
—	DE-128 (InnFocus MicroShunt)	Glaucoma	Original	U.S.						
				Europe						
In August 2016, acquired InnFocus, developer of InnFocus MicroShunt. MicroShunt is the implant to lower and sustain intraocular pressure (IOP) out for the treatment of primary open-angle glaucoma by making aqueous humor drain out.										

■ Changes from 1Q FY16 (August 2, 2016)

Dev. Code / name	Changes
DE-126	Preparing Phase 2b in U.S.
DE-128/ InnFocus MicroShunt	Acquired InnFocus, Inc., developer of InnFocus MicroShunt in August 2016.

Other consolidated information

Capital expenditures

(Millions of yen)

	Six months ended September 30, 2015	Year ended March 31, 2016	Six months ended September 30, 2016	Year ending March 31, 2017
	Actual			Forecast
Consolidated	1,793	4,474	2,864	7,070

Depreciation and amortization

(Millions of yen)

	Six months ended September 30, 2015	Year ended March 31, 2016	Six months ended September 30, 2016	Year ending March 31, 2017
	Actual			Forecast
Manufacturing cost	684	1,445	728	1,590
Selling, general and administrative expenses	513	1,035	601	1,250
R&D expenses	315	653	338	660
Consolidated total	1,512	3,133	1,667	3,500

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

Amortization on intangible assets associated with products

(Millions of yen)

	Six months ended September 30, 2015	Year ended March 31, 2016	Six months ended September 30, 2016	Year ending March 31, 2017
	Actual			Forecast
Intangible assets (Merck products)	2,581	5,186	2,645	5,310
Intangible assets (Ikervis)	255	625	336	660
Other	163	394	188	1,080
Consolidated total	2,999	6,205	3,169	7,050

R&D expenses

(Millions of yen)

	Six months ended September 30, 2015	Year ended March 31, 2016	Six months ended September 30, 2016	Year ending March 31, 2017
	Actual			Forecast
Consolidated	9,243	19,990	10,304	20,400
Percent of revenue	9.4%	10.2%	10.5%	10.2%

*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.