

## Santen Reports Fiscal 2016 Consolidated Performance

May 10, 2017 – Santen Pharmaceutical Co., Ltd. (Osaka, JAPAN, Tokyo Stock Exchange Code 4536) (Santen) today announced consolidated performance for FY16, the year ended March 31, 2017.

Boosted by sales of new products and regional expansion, Santen’s consolidated revenue in FY16 reached 199 billion yen, up 1.9% (up 7.4% excluding the impacts of foreign exchange and divestment of the anti-RA business in 2015). In the prescription pharmaceutical business which represented 92.2% of total revenue in FY16, the Japan business was able to offset the impact of NHI price cuts and grow revenue by 4.4%, excluding the anti-RA business divestiture impact. Overseas pharmaceutical revenue increased in Asia and EMEA (Europe, the Middle East and Africa) by 19% and 25%, respectively, on a local currency basis. Proactive investments in Santen’s advancing pipeline and expanding business platform caused core operating profit to decline by 7.8%.

With steady growth in Japan and continued strong performance overseas, revenue and core operating profit are forecast to increase by 9.5% and 10.9%, respectively, in FY17.

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*	FY16 actual (JPY millions)	change (YoY%)	FY17 forecast (JPY millions)	change (YoY%)
Revenue	199,096	+1.9%	218,000	+9.5%
Core operating profit	39,687	(7.8%)	44,000	+10.9%
Core net profit for the period	28,688	(1.6%)	31,200	+8.8%
Earnings per share (basic) (yen)	69.93		77.31	

IFRS	FY16 actual (JPY millions)	change (YoY%)	FY17 forecast (JPY millions)	change (YoY%)
Revenue	199,096	+1.9%	218,000	+9.5%
Operating profit	32,479	(59.5%)	37,400	+15.2%
Net profit for the period	23,054	(56.8%)	26,800	+16.2%

\* 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. 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 in IFRS but excluded from core basis results.

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 approximately 60 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](http://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, 2017

### (1) Operating results (Core basis \*1)

	Year to March 2016	Year to March 2017	% change
Revenue	195,291	199,096	+1.9%
Core operating profit	43,067	39,687	(7.8%)
Core net profit for the year	29,163	28,688	(1.6%)
Core net profit for the year attributable to owners of the company	29,163	28,694	(1.6%)
Basic core earnings per share (yen)	70.48	69.93	
Diluted core earnings per share (yen)	70.16	69.67	

### (IFRS)

	Year to March 2016	Year to March 2017	% change
Revenue	195,291	199,096	+1.9%
Operating profit	80,180	32,479	(59.5%)
Profit before tax	79,470	31,822	(60.0%)
Net profit for the year	53,373	23,054	(56.8%)
Net profit for the year attributable to owners of the company	53,373	23,061	(56.8%)
Total comprehensive income for the year	57,373	15,866	(72.3%)
Basic earnings per share (yen)	128.99	56.20	
Diluted earnings per share (yen)	128.41	55.99	
Profit ratio to equity attributable to owners of the company	22.6	9.0	
Profit before tax to total assets ratio	24.1	9.4	
Operating profit to revenue ratio	41.1	16.3	

### (2) Financial position

	March 31, 2016	March 31, 2017
Total assets	355,399	322,778
Total equity	260,009	253,884
Total equity attributable to owners of the company	260,009	253,065
Total equity attributable to owners of the company ratio	73.2%	78.4%
Equity per share attributable to owners of the company (yen)	627.78	623.06

### (3) Cash flows

	Year to March 2016	Year to March 2017
Cash flows from operating activities	22,525	10,843
Cash flows from investing activities	37,052	(28,201)
Cash flows from financing activities	(24,066)	(28,657)
Cash and cash equivalents at end of year	99,798	52,282

## 2. Dividends

	Year to March 2016	Year to March 2017	(Forecasts) Year to March 2018
Second quarter dividends per share (yen)	12.00	13.00	13.00
Year-end dividends per share (yen)	13.00	13.00	13.00
Annual dividends per share (yen)	25.00	26.00	26.00
Total dividends paid (full-year)	10,350	10,647	—
Payout ratio (consolidated)	19.4%	46.3%	39.3%
Dividends paid on equity attributable to owners of the company (consolidated)	4.4%	4.2%	—

### **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): Yes**

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

Note: 5 companies, Santen Business Services Co., Ltd., Santen Eye Care Co., Ltd., Santen Pharmaceutical (Hong Kong) Limited, SANTEN LIMITED LIABILITY COMPANY 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)

March 31, 2017 : 406,173,015

March 31, 2016 : 414,191,515

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

March 31, 2017 : 6,646

March 31, 2016 : 22,369

[ iii ] Average number of outstanding shares (during the fiscal year ended March 31)

Fiscal year ended March 31, 2017: 410,343,269

Fiscal year ended March 31, 2016: 413,786,080

#### **(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.

**(Reference)**

**1. Non-Consolidated performance for the fiscal year ended March 31, 2017**

**(1) Operating results**

	Year to March 2016	Year to March 2017	% change
Net sales	156,117	156,968	+0.5%
Operating income	30,713	31,311	+1.9%
Ordinary income	30,550	30,378	(0.6%)
Net income	51,454	24,999	(51.4%)
Net income per share (yen)	124.35	60.92	
Diluted net income per share (yen)	123.79	60.70	

Note: Above non-consolidated operating income ended March 2016 differ from consolidated operating profit ended March 2016 due to the fact that non-consolidated performance is based on Japanese GAAP and consolidated performance is based on International Financial Reporting Standards (IFRS).

**(2) Financial position**

	March 31, 2016	March 31, 2017
Total assets	334,659	299,363
Net assets	252,151	245,358
Equity ratio	75.1%	81.7%
Net assets per share (yen)	607.08	602.05

Reference: Equity at year-end:

Fiscal year ended March 31, 2017: 244,533 million yen

Fiscal year ended March 31, 2016: 251,436 million yen

**(Information regarding the implementation of audit procedures)**

These financial results are not subject to audit procedures.

**(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, 2016	Year ended March 31, 2017
<b>Revenue</b>	<b>195,291</b>	<b>199,096</b>
Cost of sales	(72,829)	(74,966)
<b>Gross profit</b>	<b>122,463</b>	<b>124,130</b>
Selling, general and administrative expenses	(59,406)	(62,193)
Research and development expenses	(19,990)	(22,786)
Amortization on intangible assets associated with products	(6,205)	(6,412)
Other income	44,999	468
Other expenses	(1,681)	(728)
<b>Operating profit</b>	<b>80,180</b>	<b>32,479</b>
Finance income	782	909
Finance expenses	(1,492)	(1,565)
<b>Profit before tax</b>	<b>79,470</b>	<b>31,822</b>
Income tax expenses	(26,097)	(8,768)
<b>Net profit for the year</b>	<b>53,373</b>	<b>23,054</b>
<b>Other comprehensive income</b>		
Items that will not be reclassified subsequently to profit of loss		
Remeasurements of defined benefit plans	(1,007)	297
Net gain on financial assets measured at fair value through other comprehensive income	7,395	(8,020)
Items that may be reclassified subsequently to profit or loss		
Foreign currency translation adjustments	(2,389)	535
Other comprehensive income	<b>4,000</b>	<b>(7,188)</b>
<b>Total comprehensive income</b>	<b>57,373</b>	<b>15,866</b>
Profit attributable to		
Owners of the company	53,373	23,061
Non-controlling interests	—	(7)
<b>Net profit for the year</b>	<b>53,373</b>	<b>23,054</b>
Total comprehensive income attributable to		
Owners of the company	57,373	15,879
Non-controlling interests	—	(13)
<b>Total comprehensive income</b>	<b>57,373</b>	<b>15,866</b>
<b>Earnings per share</b>		
Basic earnings per share (yen)	128.99	56.20
Diluted earnings per share (yen)	128.41	55.99

Core basis (JPY millions)

	Year ended March 31, 2016	Year ended March 31, 2017
Revenue	195,291	199,096
Core operating profit	43,067	39,687
Core net profit for the year	29,163	28,688
Basic core earnings per share (yen)	70.48	69.93
Diluted core earnings per share (yen)	70.16	69.67
Core profit attributable to		
Owners of the company	29,163	28,694
Non-controlling interests	—	(7)
<b>Core net profit for the year</b>	<b>29,163</b>	<b>28,688</b>

## Consolidated statement of financial position

Assets	(JPY millions)	
	March 31, 2016	March 31, 2017
<b>Non-current assets</b>		
Property, plant and equipment	27,991	28,550
Intangible assets	83,681	102,807
Financial assets	44,535	29,889
Deferred tax assets	2,345	2,396
Other non-current assets	2,109	2,124
<b>Total non-current assets</b>	<b>160,660</b>	<b>165,767</b>
<b>Current assets</b>		
Inventories	24,996	28,502
Trade and other receivables	65,998	70,970
Other financial assets	234	333
Other current assets	3,714	3,909
Cash and cash equivalents	99,798	53,297
<b>Total current assets</b>	<b>194,739</b>	<b>157,011</b>
<b>Total assets</b>	<b>355,399</b>	<b>322,778</b>

## Equity and liabilities

(JPY millions)

	March 31, 2016	March 31, 2017
<b>Equity</b>		
Share capital	7,695	7,792
Capital surplus	8,389	8,417
Treasury shares	(24)	(10)
Retained earnings	221,945	223,418
Other components of equity	22,003	13,448
<b>Total equity attributable to owners of the company</b>	<b>260,009</b>	<b>253,065</b>
<b>Non-controlling interests</b>	<b>—</b>	<b>819</b>
<b>Total equity</b>	<b>260,009</b>	<b>253,884</b>
<b>Liabilities</b>		
<b>Non-current liabilities</b>		
Financial liabilities	12,944	7,619
Net defined benefit liabilities	2,556	1,900
Provisions	1,629	1,426
Deferred tax liabilities	3,988	2,596
Other non-current liabilities	1,043	1,919
<b>Total non-current liabilities</b>	<b>22,161</b>	<b>15,460</b>
<b>Current liabilities</b>		
Trade and other payables	24,504	23,937
Other financial liabilities	19,881	17,603
Income tax payable	20,431	3,279
Provisions	1,276	1,372
Other current liabilities	7,138	7,244
<b>Total current liabilities</b>	<b>73,230</b>	<b>53,434</b>
<b>Total liabilities</b>	<b>95,391</b>	<b>68,894</b>
<b>Total equity and liabilities</b>	<b>355,399</b>	<b>322,778</b>

## Consolidated statement of changes in equity

Year ended March 31, 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
<b>Balance at April 1, 2015</b>	7,383	8,077	(18)	178,840	—	11,944
<b>Comprehensive income</b>						
Net profit for the period				53,373		
Other comprehensive income					(1,007)	7,395
<b>Total comprehensive income</b>	—	—	—	53,373	(1,007)	7,395
<b>Transactions with owners</b>						
Issuance of new shares	312	312				
Acquisition of treasury shares			(5)			
Dividends				(9,925)		
Share-based payments						
Other				(343)	1,007	(664)
<b>Total transactions with owners</b>	312	312	(5)	(10,268)	1,007	(664)
<b>Balance at March 31, 2016</b>	7,695	8,389	(24)	221,945	—	18,676

(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			
<b>Balance at April 1, 2015</b>	5,000	553	17,497	211,779	—	211,779
<b>Comprehensive income</b>						
Net profit for the period			—	53,373		53,373
Other comprehensive income	(2,389)		4,000	4,000		4,000
<b>Total comprehensive income</b>	(2,389)	—	4,000	57,373	—	57,373
<b>Transactions with owners</b>						
Issuance of new shares		(86)	(86)	538		538
Acquisition of treasury shares			—	(5)		(5)
Dividends			—	(9,925)		(9,925)
Share-based payments		249	249	249		249
Other			343	—		—
<b>Total transactions with owners</b>	—	163	506	(9,143)	—	(9,143)
<b>Balance at March 31, 2016</b>	2,611	716	22,003	260,009	—	260,009



Year ended March 31, 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
<b>Balance at April 1, 2016</b>	7,695	8,389	(24)	221,945	—	18,676
<b>Comprehensive income</b>						
Net profit for the period				23,061		
Other comprehensive income					297	(8,020)
<b>Total comprehensive income</b>	—	—	—	23,061	297	(8,020)
<b>Transactions with owners</b>						
Issuance of new shares	97	97				
Acquisition of treasury shares		(69)	(12,311)			
Disposals of treasury shares		(0)	0			
Cancellation of treasury shares		(0)	12,325	(12,325)		
Dividends				(10,751)		
Establishment of subsidiary with non-controlling interests						
Share-based payments						
Other				1,487	(297)	(1,186)
<b>Total transactions with owners</b>	97	28	14	(21,588)	(297)	(1,186)
<b>Balance at March 31, 2017</b>	7,792	8,417	(10)	223,418	—	9,470

(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			
<b>Balance at April 1, 2016</b>	2,611	716	22,003	260,009	—	260,009
<b>Comprehensive income</b>						
Net profit for the period			—	23,061	(7)	23,054
Other comprehensive income	541		(7,182)	(7,182)	(6)	(7,188)
<b>Total comprehensive income</b>	541	—	(7,182)	15,879	(13)	15,866
<b>Transactions with owners</b>						
Issuance of new shares		(24)	(24)	169		169
Acquisition of treasury shares			—	(12,380)		(12,380)
Disposals of treasury shares			—	0		0
Cancellation of treasury shares			—	—		—
Dividends			—	(10,751)		(10,751)
Establishment of subsidiary with non-controlling interests			—	—	832	832
Share-based payments		138	138	138		138
Other		(4)	(1,487)	—		—
<b>Total transactions with owners</b>	—	110	(1,373)	(22,823)	832	(21,991)
<b>Balance at March 31, 2017</b>	3,153	825	13,448	253,065	819	253,884

## Consolidated statements of cash flows

(JPY millions)

	Year ended March 31, 2016	Year ended March 31, 2017
<b>I. Cash flows from operating activities:</b>		
Net profit for the year	53,373	23,054
Depreciation and amortization	9,338	9,882
Impairment losses	395	475
Finance income and expenses	(545)	1,180
Income tax expenses	26,097	8,768
Gain on disposal of disposal groups	(44,477)	—
Decrease (increase) in trade and other receivables	(4,799)	(5,489)
Decrease (increase) in inventories	(5,388)	(4,120)
Increase (decrease) in trade and other payables	4,376	(425)
Increase (decrease) on net defined benefit liabilities	(3,974)	(200)
Other	653	913
<b>Subtotal</b>	<b>35,049</b>	<b>34,039</b>
Interest received	67	74
Dividends received	573	681
Interest paid	(98)	(52)
Income tax paid	(13,067)	(23,900)
<b>Net cash flows from (used in) operating activities</b>	<b>22,525</b>	<b>10,843</b>
<b>II. Cash flows from investing activities:</b>		
Payments into time deposits	(21)	—
Proceeds from withdrawal of time deposits	21	19
Payments for acquisition of investments	(2,210)	(478)
Proceeds from sale and redemption of investments	2,682	1,364
Increase (decrease) through acquisition of subsidiary	—	(19,064)
Payments for acquisition of property, plant and equipment	(4,299)	(4,145)
Proceeds from sales of property, plant and equipment	696	4
Payments for acquisition of intangible assets	(4,793)	(5,355)
Proceeds on disposal of disposal groups	45,000	—
Other	(25)	(545)
<b>Net cash flows from (used in) investing activities</b>	<b>37,052</b>	<b>(28,201)</b>
<b>III. Cash flows from financing activities:</b>		
Proceeds from long-term loans payable	500	3,000
Repayments of long-term loans payable	(15,133)	(9,524)
Acquisition of treasury shares	(5)	(12,380)
Proceeds from contributions of non-controlling interests	—	832
Dividends paid	(9,923)	(10,751)
Other	495	167
<b>Net cash flows from (used in) financing activities</b>	<b>(24,066)</b>	<b>(28,657)</b>
<b>IV. Net increase (decrease) in cash and cash equivalents</b>	<b>35,510</b>	<b>(46,015)</b>
<b>V. Cash and cash equivalents at the beginning of year</b>	<b>65,923</b>	<b>99,798</b>
<b>VI. Effect of exchange rate changes on cash and cash equivalents</b>	<b>(1,636)</b>	<b>(1,501)</b>
<b>VII. Cash and cash equivalents at the end of period</b>	<b>99,798</b>	<b>52,282</b>

## Segment information

Year ended March 31, 2016

(JPY millions)

	<Reportable segment> Pharmaceuticals	Other (Note:1)	Total	Adjustments	Consolidated total
Revenue:					
External customers	192,554	2,737	195,291	—	195,291
Intersegment	—	655	655	(655)	—
Total	192,554	3,392	195,946	(655)	195,291
Segment income (loss) (Note:2)	81,159	(979)	80,180	—	80,180
				Finance income	782
				Finance expenses	(1,492)
				Profit before tax	79,470

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.

Year ended March 31, 2017

(JPY millions)

	<Reportable segment> Pharmaceuticals	Other (Note:1)	Total	Adjustments	Consolidated total
Revenue:					
External customers	196,023	3,073	199,096	—	199,096
Intersegment	—	676	676	(676)	—
Total	196,023	3,749	199,771	(676)	199,096
Segment income (loss) (Note:2)	33,020	(541)	32,479	—	32,479
				Finance income	909
				Finance expenses	(1,565)
				Profit before tax	31,822

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

Year ended March 31, 2016

(JPY millions)

Pharmaceuticals business			Other businesses			Total
Prescription pharmaceuticals			OTC pharmaceuticals	Medical devices	Others	
Ophthalmics	Anti- rheumatics	Other pharmaceuticals				
172,545	3,495	5,510	11,004	2,394	343	195,291

Year ended March 31, 2017

(JPY millions)

Pharmaceuticals business			Other businesses			Total
Prescription pharmaceuticals			OTC pharmaceuticals	Medical devices	Others	
Ophthalmics	Anti- rheumatics	Other pharmaceuticals				
181,859	—	1,610	12,553	2,536	537	199,096

## Geographic information

Revenues

(JPY millions)

	Japan	Europe	U.S.	Asia	Others	Total
For the year ended March 31, 2016	141,849	25,562	5,265	22,601	14	195,291
For the year ended March 31, 2017	145,358	28,521	1,433	23,738	46	199,096

## Revenue of major pharmaceuticals

(JPY millions)

Brand name Generic name/formulation	Therapeutic category	Region	Year ended March 31, 2017				Year ending March 31, 2018	
			Six months ended September 30, 2016 Actual	Changes from same period of previous year	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	6,914	(13.9%)	12,884	(9.6%)	13,945	8.2%
		Japan	2,601	(20.7%)	4,660	(21.3%)	4,308	(7.5%)
		Asia	3,704	(8.7%)	6,980	(0.3%)	8,252	18.2%
		Europe	610	(12.2%)	1,245	(6.5%)	1,384	11.2%
Tarivid ofloxacin/ophthalmic solution	Bacterial conjunctivitis	Total	858	(21.0%)	1,541	(12.5%)	1,455	(5.6%)
		Japan	312	(16.8%)	559	(16.9%)	472	(15.6%)
		Asia	547	(23.2%)	982	(9.8%)	983	0.1%
		Europe	-	-	-	-	-	-
Tapcom tafluprost-timolol maleate/ combination ophthalmic solution	Glaucoma	Total	1,282	101.4%	2,798	82.4%	3,800	35.8%
		Japan	1,116	99.0%	2,256	63.4%	2,587	14.6%
		Asia	12	-	38	-	90	137.1%
		Europe	155	103.1%	504	229.3%	1,124	122.9%
Tapros tafluprost/ophthalmic solution	Glaucoma	Total	8,186	5.9%	16,406	4.9%	18,115	10.4%
		Japan	4,961	7.5%	9,592	4.6%	10,489	9.3%
		Asia	570	3.6%	1,227	11.8%	1,613	31.5%
		Europe	2,654	3.5%	5,587	4.1%	5,985	7.1%
		Other	-	-	-	-	28	-
Cosopt dorzolamide hydrochloride-timolol maleate/combination ophthalmic solution	Glaucoma	Total	11,176	14.0%	22,164	7.7%	23,013	3.8%
		Japan	5,887	3.2%	11,366	1.4%	11,468	0.9%
		Asia	1,303	2.7%	2,669	7.1%	2,913	9.1%
		Europe	3,986	40.9%	8,122	18.1%	8,476	4.4%
		Other	-	-	6	-	156	-
Timoptol timolol maleate/ ophthalmic solution	Glaucoma	Total	845	(18.1%)	1,509	(21.8%)	1,430	(5.2%)
		Japan	522	(18.0%)	967	(18.1%)	853	(11.8%)
		Asia	63	(14.5%)	119	(14.8%)	182	52.3%
		Europe	260	(19.1%)	422	(30.6%)	395	(6.2%)
Timoptol XE timolol maleate/ long-acting ophthalmic solution	Glaucoma	Total	1,173	(9.5%)	2,382	(3.3%)	2,179	(8.5%)
		Japan	867	(13.1%)	1,614	(14.4%)	1,450	(10.2%)
		Asia	41	(8.0%)	88	0.8%	42	(52.4%)
		Europe	265	4.7%	679	38.8%	687	1.1%
Trusopt dorzolamide hydrochloride/ ophthalmic solution	Glaucoma	Total	2,159	(1.6%)	4,343	(4.8%)	3,906	(10.1%)
		Japan	914	(19.2%)	1,731	(18.6%)	1,396	(19.3%)
		Asia	137	(53.8%)	271	(39.3%)	280	3.3%
		Europe	1,108	44.8%	2,333	17.2%	2,194	(6.0%)
Other	-	-	9	-	36	298.4%		
Detantol bunazosin hydrochloride/ ophthalmic solution	Glaucoma	Japan	562	(5.3%)	1,054	(5.6%)	926	(12.1%)
Rescula isopropyl unoprostone/ ophthalmic solution	Glaucoma	Japan	870	(10.0%)	1,633	(11.5%)	1,641	0.5%
Alesion epinastine hydrochloride/ ophthalmic solution	Allergy	Japan	4,066	48.2%	12,235	29.0%	14,926	22.0%
Flumetholon fluorometholone/ ophthalmic solution	Inflammation	Total	1,781	(11.6%)	3,347	(11.3%)	3,425	2.3%
		Japan	1,104	(14.2%)	2,224	(16.2%)	2,123	(4.5%)
		Asia	677	(7.0%)	1,123	0.3%	1,302	15.9%
Kary Uni pirenoxine/ ophthalmic solution	Senile cataract	Total	2,120	(6.5%)	4,124	(1.5%)	4,439	7.7%
		Japan	1,502	0.4%	2,833	(2.3%)	2,776	(2.0%)
		Asia	618	(20.0%)	1,291	0.3%	1,663	28.8%
Opegan Hi sodium hyaluronate/ adjuvant for ophthalmic operations	Adjuvant for ophthalmic operations	Japan	1,187	(11.1%)	2,285	(11.0%)	2,288	0.1%
Eylea afibercept/ solutiion for intravitreal injection	Intravitreal VEGF inhibitor	Japan	22,820	16.6%	45,155	12.9%	46,199	2.3%
Hyalein sodium hyaluronate/ophthalmic solution	Dry eye	Total	9,308	(10.6%)	17,595	(11.4%)	17,483	(0.6%)
		Japan	6,256	(17.4%)	11,852	(18.2%)	10,743	(9.4%)
		Asia	3,052	7.8%	5,743	6.9%	6,740	17.4%
Diquas diquafosol sodium/ophthalmic solution	Dry eye	Total	5,795	26.6%	11,940	24.0%	14,574	22.1%
		Japan	5,403	27.7%	11,016	24.1%	12,642	14.8%
		Asia	391	13.7%	924	23.1%	1,932	109.0%
Ikervis ciclosporin/ophthalmic solution	Dry eye	Total	452	185.2%	1,303	73.5%	2,344	79.9%
		Asia	-	-	2	-	64	-
		Europe	452	185.2%	1,301	73.2%	2,226	71.1%
		North America	-	-	-	-	49	-
		Other	-	-	-	-	6	-
Cationorm	Dry eye	Total	755	40.9%	1,835	26.3%	2,587	41.0%
		Asia	83	27.1%	206	23.4%	344	67.0%
		Europe	619	44.9%	1,318	28.1%	1,894	43.7%
		North America	44	8.1%	280	15.7%	287	2.4%
		Other	8	270.9%	31	114.9%	62	101.7%
OTC pharmaceuticals			6,087	24.1%	12,553	14.1%	12,900	2.8%
Exchange rate (yen)	Major currency			Year to March 2016	Year to March 2017	Year to March 2018(Forecasts)		
	US dollar		120.45		108.64	110.00		
	Euro		132.46		118.96	120.00		
	RMB		19.05		16.14	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

## ■ Pipeline of prescription pharmaceuticals (Clinical Stage)

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
tafluprost	DE-085	Glaucoma/ Ocular hypertension	Co-development with Asahi Glass	China						Mar-2016

A prostaglandin F<sub>2α</sub> derivative for the treatment of glaucoma and ocular hypertension. Since December 2008, launched in Japan, Europe and Asia. Launched in China in March 2016.

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		
				Asia						Feb-2016

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.

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		

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.

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
tafluprost/ timolol maleate	DE-111	Glaucoma/ Ocular hypertension	Co-development with Asahi Glass	Asia						Apr-2016

A fixed dose combination drug of a prostaglandin F<sub>2α</sub> derivative and a beta-adrenergic receptor blocker. Launched in Japan in November 2014. Launched successively in European countries since October 2014 and launched since January 2015. Launched in Korea in April 2016. NDA filed in Asian countries successively, and approved in some countries including Thailand.

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

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.

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
tafluprost	DE-118	Glaucoma/ Ocular hypertension	Co-development with Asahi Glass	Asia						Apr-2016

A prostaglandin F<sub>2α</sub> derivative for the treatment of glaucoma and ocular hypertension. Preservative-free, single dose type product. Launched in Japan in October 2013. Launched in Asian countries since April, 2016.

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 1/2)					

An intravitreal injection of anti-endothelin antibody. Started Phase 1/2 in the U.S. in September 2015 and preparing Phase 2a.

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 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 the U.S. and Japan.

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
—	DE-128	Glaucoma	Original	U.S.	(Phase 2/3)					
—	(InnFocus MicroShunt)			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.

Generic name	Dev. name	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
ciclosporin	Cyclokat	Severe keratitis in patients with dry eye	Original	Europe						Jul-2015
				U.S.						
				Asia						Nov-2016
				Others						Apr-2016
<p>An ophthalmic emulsion which improves severe keratitis in adult patients with dry eye by 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 .</p>										

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

#### ■ Changes from Q3 FY16 (February 7, 2017)

Dev. code / name	Changes
DE-090	The company has discontinued development upon reassessment of the project's PTS.
DE-109	NDA filed in the U.S. in February 2017.
DE-117	Started Phase 3 in Asia in December 2016.
DE-120	The company has discontinued development upon reassessment of the project's PTS.
Cyclokat	Approved in some countries including Korea in March 2017.
Cortiject	The company has discontinued development upon reassessment of the project's PTS.

## Other consolidated information

### Capital expenditures

(JPY millions)

	Six months ended September 30, 2016	Year ended March 31, 2017	Year ending March 31, 2018
	Actual		Forecast
Consolidated	2,864	5,216	7,660

### Depreciation and amortization

(JPY millions)

	Six months ended September 30, 2016	Year ended March 31, 2017	Year ending March 31, 2018
	Actual		Forecast
Manufacturing cost	728	1,515	1,880
Selling, general and administrative expenses	601	1,246	1,270
Research and development expenses	338	709	680
Consolidated total	1,667	3,470	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)

	Six months ended September 30, 2016	Year ended March 31, 2017	Year ending March 31, 2018
	Actual		Forecast
Intangible assets (Merck products)	2,645	5,357	5,590
Intangible assets (Ikervis)	336	674	680
Other	188	381	350
Consolidated total	3,169	6,412	6,620

### Research and development expenses

(JPY millions)

	Six months ended September 30, 2016	Year ended March 31, 2017	Year ending March 31, 2018
	Actual		Forecast
Consolidated	10,304	22,786	25,000
Percent of revenue	10.5%	11.4%	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.