

Santen Reports Consolidated Results for Q2 Fiscal 2018

November 7, 2018 – Santen Pharmaceutical Co., Ltd. (Osaka, JAPAN, Tokyo Stock Exchange Code 4536) (Santen) today announced consolidated performance for Q2 FY18, the cumulative six month period ended September 30, 2018.

Boosted by the sales of products across a range of ophthalmology treatment areas and including especially strong growth overseas, Santen’s consolidated revenue in Q2 FY18 reached 114.3 billion yen, an increase of 3.2% year-on-year. In Japan, Santen’s business growth of key products was mitigated by the impact of government mandated prescription pharmaceutical price cuts and other transitory factors. Outside Japan, pharmaceutical revenue was robust in Asia and EMEA regions with growth of 28.8% and 4.6%, respectively, in yen terms.

For the current fiscal year ending March 31, 2019, forecasts issued in May 2018 are unchanged as contributions from key products in Japan and globally are expected to overcome the negative impact of Japanese price cuts, with consolidated revenue and core operating profit forecast to increase by 5.4% and 5.8%, 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*	Q2 FY18** actual (JPY millions)	change (YoY%)	FY18 forecast (JPY millions)	change (YoY%)
Revenue	114,344	+3.2%	237,000	+5.4%
Core operating profit	24,135	(1.0%)	48,000	+5.8%
Core net profit for the period	17,799	(0.6%)	35,300	+5.5%
Earnings per share (basic)	43.74		87.26	

IFRS	Q2 FY18** actual (JPY millions)	change (YoY%)	FY18 forecast (JPY millions)	change (YoY%)
Revenue	114,344	+3.2%	237,000	+5.4%
Operating profit	20,825	(1.0%)	40,700	+5.2%
Net profit for the period	14,376	(5.7%)	30,400	(13.8%)

* 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.

** Santen results herein describe Q2 results cumulatively as the six month period ended September 30, 2018.

Additional Santen investor relations information can be found here: <http://www.santen.com/en/ir/>.

About Santen

As a global 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 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.

(JPY millions)

1. Consolidated performance for the six months ended September 30, 2018

(1) Operating results (Core basis)

	Six months ended September 30, 2017	Six months ended September 30, 2018	% change
Revenue	110,774	114,344	+3.2%
Core operating profit	24,386	24,135	(1.0%)
Core net profit for the period	17,901	17,799	(0.6%)
Core net profit for the period attributable to owners of the company	17,912	17,803	(0.6%)
Basic core earnings per share (yen)	44.09	43.75	
Diluted core earnings per share (yen)	43.93	43.62	

(IFRS)

	Six months ended September 30, 2017	Six months ended September 30, 2018	% change
Revenue	110,774	114,344	+3.2%
Operating profit	21,039	20,825	(1.0%)
Profit before tax	20,686	19,790	(4.3%)
Net profit for the period	15,246	14,376	(5.7%)
Net profit for the period attributable to owners of the company	15,257	14,380	(5.7%)
Total comprehensive income for the period	19,981	22,294	+11.6%
Basic earnings per share (yen)	37.56	35.34	
Diluted earnings per share (yen)	37.42	35.23	

(2) Financial position

	March 31, 2018	September 30, 2018
Total assets	388,463	400,030
Total equity	287,557	304,597
Total equity attributable to owners of the company	285,823	302,914
Total equity attributable to owners of the company ratio	73.6%	75.7%
Equity per share attributable to owners of the company (yen)	702.54	744.22

2. Dividends

	Year to March 2018	Year to March 2019	(Forecasts) Year to March 2019
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, 2019

(Core basis)

	Year to March 2019	% change
Revenue	237,000	+5.4%
Core operating profit	48,000	+5.8%
Core net profit for the year	35,300	+5.5%
Core earnings per share (yen)	87.26	

(IFRS)

	Year to March 2019	% change
Revenue	237,000	+5.4%
Operating profit	40,700	+5.2%
Profit before tax	41,300	+5.2%
Net profit for the year	30,400	(13.8%)
Basic earnings per share (yen)	75.21	

***Others**

(1) Changes in significant subsidiaries during the term

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

(2) Changes in accounting policies and accounting estimates

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

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

- [i] Number of shares outstanding at the end of period (including treasury shares)
 - September 30, 2018: 407,102,254
 - March 31, 2018 : 406,847,515
- [ii] Number of treasury shares at the end of period
 - September 30, 2018: 7,786
 - March 31, 2018 : 7,411
- [iii] Average number of outstanding shares (during the fiscal year ended September 30)
 - Second quarter ended September 30, 2018: 406,937,690
 - Second quarter ended September 30, 2017: 406,235,822

(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.

Quarterly consolidated statements of income and comprehensive income

IFRS basis	(JPY millions)	
	Six months ended September 30, 2017	Six months ended September 30, 2018
Revenue	110,774	114,344
Cost of sales	(42,971)	(45,772)
Gross profit	67,803	68,573
Selling, general and administrative expenses	(31,676)	(33,474)
Research and development expenses	(11,742)	(10,964)
Amortization on intangible assets associated with products	(3,324)	(3,473)
Other income	200	259
Other expenses	(223)	(96)
Operating profit	21,039	20,825
Finance income	497	547
Finance expenses	(851)	(1,581)
Profit before tax	20,686	19,790
Income tax expenses	(5,440)	(5,414)
Net profit for the period	15,246	14,376
Other comprehensive income for the period		
Items that will not be reclassified subsequently to profit or loss		
Remeasurements of defined benefit plans	—	—
Net gain or loss on financial assets measured at fair value through other comprehensive income	1,544	3,907
Items that may be reclassified subsequently to profit or loss		
Foreign currency translation adjustments	3,192	4,011
Other comprehensive income	4,736	7,918
Total comprehensive income	19,981	22,294
Profit attributable to		
Owners of the company	15,257	14,380
Non-controlling interests	(11)	(4)
Net profit for the period	15,246	14,376
Total comprehensive income attributable to		
Owners of the company	19,931	22,345
Non-controlling interests	51	(51)
Total comprehensive income	19,981	22,294
Earnings per share		
Basic earnings per share (yen)	37.56	35.34
Diluted earnings per share (yen)	37.42	35.23

Core basis	(JPY millions)	
	Six months ended September 30, 2017	Six months ended September 30, 2018
Revenue	110,774	114,344
Core operating profit	24,386	24,135
Core net profit for the period	17,901	17,799
Basic core earnings per share (yen)	44.09	43.75
Diluted core earnings per share (yen)	43.93	43.62
Core profit attributable to		
Owners of the company	17,912	17,803
Non-controlling interests	(11)	(4)
Core net profit for the period	17,901	17,799

Quarterly consolidated statement of financial position

Assets	(JPY millions)	
	March 31, 2018	September 30, 2018
Non-current assets		
Property, plant and equipment	29,706	31,498
Intangible assets	134,495	135,506
Financial assets	35,775	41,793
Deferred tax assets	2,264	2,288
Other non-current assets	2,855	2,004
Total non-current assets	205,095	213,089
Current assets		
Inventories	30,636	31,837
Trade and other receivables	78,654	76,235
Other financial assets	472	335
Other current assets	4,322	3,296
Cash and cash equivalents	69,283	75,237
Total current assets	183,367	186,941
Total assets	388,463	400,030

Equity and liabilities

(JPY millions)

	March 31, 2018	September 30, 2018
Equity		
Equity attributable to owners of the company		
Share capital	8,032	8,186
Capital surplus	8,657	8,688
Treasury shares	(11)	(12)
Retained earnings	249,225	258,316
Other components of equity	19,921	27,736
Total equity attributable to owners of the company	285,823	302,914
Non-controlling interests	1,734	1,683
Total equity	287,557	304,597
Liabilities		
Non-current liabilities		
Financial liabilities	21,244	23,016
Net defined benefit liabilities	1,804	2,319
Provisions	1,367	1,388
Deferred tax liabilities	12,909	15,247
Other non-current liabilities	1,380	1,677
Total non-current liabilities	38,704	43,648
Current liabilities		
Trade and other payables	29,743	28,425
Other financial liabilities	14,404	9,635
Income tax payable	7,656	5,153
Provisions	1,508	557
Other current liabilities	8,890	8,015
Total current liabilities	62,201	51,785
Total liabilities	100,905	95,433
Total equity and liabilities	388,463	400,030

Quarterly consolidated statement of changes in equity

Six months ended September 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)	223,283	—	9,470
Comprehensive income						
Net profit for the period				15,257		
Other comprehensive income						1,544
Total comprehensive income for the period	—	—	—	15,257	—	1,544
Transactions with owners						
Issuance of new shares	65	65				
Acquisition of treasury shares			(1)			
Dividends				(5,280)		
Change in equity of subsidiary with non-controlling interests						
Share-based payments						
Other				1		(1)
Total transactions with owners	65	65	(1)	(5,279)	—	(1)
Balance at September 30, 2017	7,856	8,482	(10)	233,260	—	11,013

(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	5,332	825	15,628	255,110	819	255,929
Comprehensive income						
Net profit for the period			—	15,257	(11)	15,246
Other comprehensive income	3,130		4,674	4,674	62	4,736
Total comprehensive income for the period	3,130	—	4,674	19,931	51	19,981
Transactions with owners						
Issuance of new shares		(16)	(16)	113		113
Acquisition of treasury shares			—	(1)		(1)
Dividends			—	(5,280)		(5,280)
Change in equity of subsidiary with non-controlling interests			—	—	838	838
Share-based payments		218	218	218		218
Other			(1)	—		—
Total transactions with owners	—	202	201	(4,950)	838	(4,112)
Balance at September 30, 2017	8,462	1,027	20,503	270,091	1,708	271,798

Six months ended September 30, 2018

(JPY millions)

	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity	
					Remeasurements of defined benefit plans	Net gain or loss on financial assets measured at fair value through other comprehensive income
Balance at April 1, 2018	8,032	8,657	(11)	249,225	—	14,364
Comprehensive income						
Net profit for the period				14,380		
Other comprehensive income						3,907
Total comprehensive income for the period	—	—	—	14,380	—	3,907
Transactions with owners						
Issuance of new shares	87	87				
Acquisition of treasury shares			(1)			
Dividends				(5,289)		
Share-based payments	67	(55)				
Total transactions with owners	154	31	(1)	(5,289)	—	—
Balance at September 30, 2018	8,186	8,688	(12)	258,316	—	18,270

(JPY millions)

	Other components of equity			Total equity attributable to owners of the company	Non-controlling interests	Total equity
	Foreign currency translation adjustments	Subscription rights to shares	Total			
Balance at April 1, 2018	4,583	975	19,921	285,823	1,734	287,557
Comprehensive income						
Net profit for the period			—	14,380	(4)	14,376
Other comprehensive income	4,058		7,965	7,965	(47)	7,918
Total comprehensive income for the period	4,058	—	7,965	22,345	(51)	22,294
Transactions with owners						
Issuance of new shares		(150)	(150)	23		23
Acquisition of treasury shares			—	(1)		(1)
Dividends			—	(5,289)		(5,289)
Share-based payments			—	12		12
Total transactions with owners	—	(150)	(150)	(5,254)	—	(5,254)
Balance at September 30, 2018	8,641	825	27,736	302,914	1,683	304,597

Quarterly consolidated statements of cash flows

(JPY millions)

	Six months ended September 30, 2017	Six months ended September 30, 2018
I . Cash flows from operating activities:		
Net profit for the period	15,246	14,376
Depreciation and amortization	5,384	5,510
Impairment losses	115	—
Finance expenses (income)	(11)	(11)
Income tax expenses	5,440	5,414
Decrease (increase) in trade and other receivables	(3,140)	2,477
Decrease (increase) in inventories	1,192	(1,158)
Increase (decrease) in trade and other payables	2,383	(1,341)
Increase (decrease) in provisions and net defined benefit liabilities	265	(445)
Other	(2,143)	(338)
Subtotal	24,732	24,486
Interest received	47	103
Dividends received	293	259
Interest paid	(18)	(6)
Income tax paid	(3,321)	(7,594)
Net cash flows from (used in) operating activities	21,732	17,249
II . Cash flows from investing activities:		
Payments for acquisition of investments	(5)	(210)
Proceeds from sales of investments	2	—
Payments for acquisition of property, plant and equipment	(1,692)	(2,863)
Payments for acquisition of intangible assets	(2,284)	(750)
Other	(11)	(147)
Net cash flows from (used in) investing activities	(3,991)	(3,971)
III . Cash flows from financing activities:		
Proceeds from long-term loans	—	245
Repayments of long-term loans	(4,575)	(2,908)
Capital contribution from non-controlling interests	838	—
Dividends paid	(5,279)	(5,288)
Other	111	21
Net cash flows from (used in) financing activities	(8,905)	(7,930)
IV . Net increase (decrease) in cash and cash equivalents	8,836	5,348
V . Cash and cash equivalents at the beginning of period	52,282	69,283
VI . Effect of exchange rate changes on cash and cash equivalents	727	606
VII . Cash and cash equivalents at the end of period	61,846	75,237

Revenue of major pharmaceuticals

(JPY millions)

Brand name Generic name/formulation	Therapeutic category	Region	Year ended March 31, 2018				Year ending March 31, 2019			
			Six months ended September 30, 2017 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, 2018 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	7,658	10.8%	14,944	16.0%	8,076	5.4%	15,443	3.3%
		Japan	2,318	(10.9%)	4,105	(11.9%)	1,754	(24.3%)	3,415	(16.8%)
		Asia	4,561	23.1%	9,225	32.2%	5,555	21.8%	10,154	10.1%
		EMEA	780	27.9%	1,614	29.7%	766	(1.7%)	1,874	16.1%
Tarivid ofloxacin/ophthalmic solution	Bacterial conjunctivitis	Total	882	2.8%	1,581	2.6%	795	(9.9%)	1,467	(7.2%)
		Japan	284	(9.0%)	508	(9.2%)	266	(6.1%)	418	(17.6%)
		Asia	599	9.6%	1,073	9.3%	529	(11.7%)	1,049	(2.2%)
		Total	1,875	46.2%	3,892	39.1%	2,307	23.0%	4,880	25.4%
Tapcom tafluprost-timolol maleate/ combination ophthalmic solution	Glaucoma	Total	1,265	13.4%	2,479	9.9%	1,282	1.3%	2,454	(1.0%)
		Japan	64	438.5%	158	317.6%	142	122.8%	219	38.4%
		Asia	547	253.7%	1,255	148.8%	883	61.6%	2,208	75.9%
		Total	8,960	9.5%	17,844	8.8%	9,094	1.5%	18,883	5.8%
Tapros tafluprost/ophthalmic solution	Glaucoma	Total	4,936	(0.5%)	9,610	0.2%	4,828	(2.2%)	9,686	0.8%
		Japan	880	54.4%	1,807	47.3%	1,043	18.5%	2,026	12.1%
		Asia	3,144	18.4%	6,427	15.0%	3,223	2.5%	7,171	11.6%
		Total	12,163	8.8%	24,200	9.2%	11,473	(5.7%)	21,202	(12.4%)
Cosopt dorzolamide hydrochloride-timolol maleate/combination ophthalmic solution	Glaucoma	Total	5,915	0.5%	11,403	0.3%	4,933	(16.6%)	8,957	(21.4%)
		Japan	1,583	21.5%	3,197	19.8%	1,801	13.8%	3,317	3.8%
		Asia	4,666	17.1%	9,600	18.1%	4,739	1.6%	8,928	(7.0%)
		Total	780	(7.6%)	1,451	(3.8%)	523	(33.0%)	990	(31.8%)
Timoptol timolol maleate/ ophthalmic solution	Glaucoma	Total	437	(16.3%)	787	(18.7%)	263	(39.9%)	470	(40.3%)
		Japan	60	(5.1%)	116	(2.7%)	57	(4.3%)	112	(3.3%)
		Asia	283	9.2%	548	30.1%	203	(28.4%)	408	(25.6%)
		Total	1,165	(0.7%)	2,221	(6.8%)	988	(15.2%)	1,976	(11.0%)
Timoptol XE timolol maleate/ long-acting ophthalmic solution	Glaucoma	Total	753	(13.1%)	1,407	(12.9%)	616	(18.2%)	1,203	(14.5%)
		Japan	52	26.2%	105	19.1%	51	(0.8%)	109	3.6%
		Asia	360	36.0%	709	4.4%	320	(11.1%)	664	(6.3%)
		Total	2,276	5.4%	4,677	7.7%	2,293	0.8%	4,547	(2.8%)
Trusopt dorzolamide hydrochloride/ ophthalmic solution	Glaucoma	Total	866	(5.3%)	1,641	(5.2%)	769	(11.2%)	1,446	(11.9%)
		Japan	152	11.0%	327	20.9%	198	30.3%	462	41.3%
		Asia	1,258	13.6%	2,709	15.7%	1,327	5.4%	2,639	(2.6%)
		Total	788	(9.4%)	1,467	(10.1%)	634	(19.5%)	1,256	(14.4%)
Rescula isopropyl unoprostone/ ophthalmic solution	Glaucoma	Total	788	(9.4%)	1,467	(10.1%)	634	(19.5%)	1,256	(14.4%)
		Japan	788	(9.4%)	1,467	(10.1%)	634	(19.5%)	1,256	(14.4%)
Alesion epinastine hydrochloride/ ophthalmic solution	Allergy	Total	5,088	25.1%	16,851	37.7%	4,893	(3.8%)	17,727	5.2%
		Japan	5,088	25.1%	16,851	37.7%	4,893	(3.8%)	17,727	5.2%
Flumetholon fluorometholone/ ophthalmic solution	Inflammation	Total	1,843	3.5%	3,497	4.5%	1,747	(5.2%)	3,141	(10.2%)
		Japan	1,059	(4.1%)	2,113	(5.0%)	769	(27.4%)	1,652	(21.8%)
		Asia	784	15.8%	1,385	23.2%	978	24.8%	1,490	7.6%
Kary Uni pirenoxine/ ophthalmic solution	Senile cataract	Total	2,428	14.5%	4,413	7.0%	2,117	(12.8%)	4,398	(0.3%)
		Japan	1,446	(3.7%)	2,741	(3.2%)	1,343	(7.1%)	2,644	(3.6%)
		Asia	982	58.8%	1,672	29.6%	774	(21.2%)	1,755	4.9%
Oftan Catachrom cytochrome C, adenosine, nicotinamide/ ophthalmic solution	Senile cataract	Total	1,449	119.2%	2,695	21.2%	1,177	(18.7%)	2,800	3.9%
		EMEA	1,449	119.2%	2,695	21.2%	1,177	(18.7%)	2,800	3.9%
Opegan Hi sodium hyaluronate/ adjunct for ophthalmic operations	Adjuvant for ophthalmic operations	Total	1,192	0.4%	2,304	0.8%	1,065	(10.7%)	2,109	(8.5%)
		Japan	1,192	0.4%	2,304	0.8%	1,065	(10.7%)	2,109	(8.5%)
Eylea * aflibercept/ solution for intravitreal injection	Intravitreal VEGF inhibitor	Total	26,044	14.1%	51,517	14.1%	28,020	7.6%	54,473	5.7%
		Japan	26,044	14.1%	51,517	14.1%	28,020	7.6%	54,473	5.7%
Hyalain sodium hyaluronate/ophthalmic solution	Dry eye	Total	9,453	1.6%	18,170	3.3%	10,445	10.5%	17,708	(2.5%)
		Japan	5,738	(8.3%)	10,772	(9.1%)	4,518	(21.3%)	8,541	(20.7%)
		Asia	3,716	21.7%	7,397	28.8%	5,927	59.5%	9,167	23.9%
Diquas diqiafosol sodium/ophthalmic solution	Dry eye	Total	7,179	23.9%	14,286	19.6%	7,679	7.0%	16,087	12.6%
		Japan	6,447	19.3%	12,822	16.4%	6,963	8.0%	14,463	12.8%
		Asia	732	86.9%	1,463	58.3%	716	(2.1%)	1,625	11.0%
Ikervis ciclosporin/ophthalmic solution	Dry eye	Total	1,012	123.9%	2,049	57.2%	1,561	54.2%	2,880	40.6%
		Asia	1	-	68	-	195	-	327	377.0%
		EMEA	1,011	123.6%	1,981	52.2%	1,366	35.1%	2,553	28.9%
Cationorm	Dry eye	Total	939	24.4%	2,092	14.0%	1,153	22.9%	3,116	49.0%
		Asia	88	43.3%	199	72.3%	79	(9.9%)	173	(13.2%)
		EMEA	798	23.0%	1,670	16.1%	977	22.5%	2,713	62.5%
		US	52	18.8%	223	(20.4%)	97	84.4%	230	3.0%
OTC pharmaceuticals		Total	7,713	26.7%	14,594	16.3%	7,566	(1.9%)	16,498	13.0%
		Japan	7,560	25.3%	14,301	15.1%	7,418	(1.9%)	16,144	12.9%
		Asia	153	178.7%	293	121.8%	148	(3.4%)	355	20.8%

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

Exchange rate (yen)	Major currency	2nd quarter ended September 30, 2017	Fiscal year ended March 31, 2018	2nd quarter ended September 30, 2018	Fiscal year to March 31, 2019(Forecasts)
	US dollar	111.18	110.94	110.21	110.00
	Euro	126.76	129.92	129.81	130.00
	CNY	16.43	16.84	16.70	17.00

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 November 7

■ 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.

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
sirolimus	DE-109	Uveitis	Original	U.S.						
				Japan						
				Europe						
				Asia				Apr-2015		

An intravitreal injection with immunosuppressive effect, anti-angiogenic effect, etc. Planning to start an additional clinical trial in November 2018 in the U.S. NDA filed in April 2015 in Asia.

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						Sep-2018

An H₁ 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.

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					Sep-2018	
				Asia						

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. Received manufacturing and marketing approval in September 2018 in Japan. Plan to be listed on NHI price list and launch soon after. Started Phase 3 in December 2016 and planning to complete in the 2nd half of FY2018 in Asia.

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)				

An intravitreal injection of anti-endothelin antibody. Started Phase 2a in July 2017 and planning to complete in January ~ June 2019 for development in the U.S.

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)				

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.

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
atropine sulfate	DE-127	Myopia	Singapore Health Services, Nanyang Technological University	Asia						

Muscarinic antagonist which reduces juvenile myopia progression. Started Phase 2 in November 2017 and planning to complete in the 2nd half of FY2019 in Asia.

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

In August 2016, acquired InnFocus, developer of MicroShunt. 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. Conducting Phase 2/3 in the U.S. and Europe in advance of application to FDA and planning to complete 2018-2019. Planning U.S. launch in 2020 ~ 2021. Received CE Mark in Europe.

Generic name	Dev. name	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
ciclosporin	DE-076B (Cyclokat)	Severe keratitis in patients with dry eye	Original	U.S.						
				Asia						Dec-2017

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 July 2015 in Germany and U.K. with successive launches following in European countries. Launched in December 2017 in Thailand and Korea with successive launches following in Asian countries.

Generic name	Dev. name	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
ciclosporin	DE-076C (Vekacia)	Vernal keratoconjunctivitis	Original	Europe						Oct-2018
An ophthalmic emulsion which improves vernal keratoconjunctivitis by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue absorption. Received the Marketing Authorization Application approval from the European Commission Agency in July 2018 and launched in October 2018 in U.K.										

Generic name	Dev. name	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
latanoprost	DE-130A (Catioprost)	Glaucoma/ Ocular hypertension	Original	Europe						
An ophthalmic emulsion of a prostaglandin F2 α derivative, for the treatment of glaucoma and ocular hypertension.										

■ Changes from Q1 FY18 (August 1, 2018)

Dev. code / name	Changes
DE-089	Launched in September 2018 in China.
DE-114A	Filed for manufacturing and marketing approval in September 2018 in Japan.
DE-117	Started Phase 3 in September 2018 in the U.S. Received manufacturing and marketing approval in September 2018 in Japan.
DE-076C (Vekacia)	Launched in October 2018 in U.K.

Other consolidated information

Capital expenditures

(JPY millions)

	Six months ended September 30, 2017	Year ended March 31, 2018	Six months ended September 30, 2018	Year ending March 31, 2019
	Actual			Forecast
Consolidated	2,731	5,445	3,233	9,000

Depreciation and amortization

(JPY millions)

	Six months ended September 30, 2017	Year ended March 31, 2018	Six months ended September 30, 2018	Year ending March 31, 2019
	Actual			Forecast
Manufacturing cost	962	1,950	946	2,040
Selling, general and administrative expenses	717	1,453	765	1,520
R&D expenses	381	752	326	700
Consolidated total	2,060	4,155	2,037	4,260

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, 2017	Year ended March 31, 2018	Six months ended September 30, 2018	Year ending March 31, 2019
	Actual			Forecast
Intangible assets (Merck products)	2,760	5,592	2,904	5,810
Intangible assets (Ikervis)	359	736	368	740
Other	205	412	201	380
Consolidated total	3,324	6,740	3,473	6,930

Research and Development expenses

(JPY millions)

	Six months ended September 30, 2017	Year ended March 31, 2018	Six months ended September 30, 2018	Year ending March 31, 2019
	Actual			Forecast
Consolidated	11,742	24,398	10,964	25,000
Percent of revenue	10.6%	10.8%	9.6%	10.5%

*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.