

February 5, 2019

Santen Pharmaceutical Co., Ltd.

Code : 4536

URL <http://www.santen.com>

Third Quarter Financial Results for the Fiscal Year Ending March 31, 2019 [IFRS] (Consolidated)

Akira Kurokawa, Chairman and Chief Executive Officer

Contact : Christopher Hohman, General Manager, Corporate Communications Group

Tel : +81-6-4802-9360

E-mail : ir@santen.co.jp

(JPY millions)

1. Consolidated performance for the nine months ended December 31, 2018

(1) Operating results

(Core basis *1)

	Nine months ended December 31, 2017	Nine months ended December 31, 2018	% change
Revenue	168,592	173,210	+2.7%
Core operating profit	35,042	35,082	+0.1%
Core net profit for the period	26,231	25,655	(2.2%)
Core net profit for the period attributable to owners of the company	26,216	25,663	(2.1%)
Basic core earnings per share (yen)	64.52	63.06	
Diluted core earnings per share (yen)	64.28	62.87	

(IFRS)

	Nine months ended December 31, 2017	Nine months ended December 31, 2018	% change
Revenue	168,592	173,210	+2.7%
Operating profit	30,087	33,657	+11.9%
Profit before tax	29,539	32,405	+9.7%
Net profit for the period	27,348	23,367	(14.6%)
Net profit for the period attributable to owners of the company	27,332	23,376	(14.5%)
Total comprehensive income for the period	34,602	21,732	(37.2%)
Basic earnings per share (yen)	67.27	57.44	
Diluted earnings per share (yen)	67.02	57.26	

(2) Financial position

	March 31, 2018	December 31, 2018
Total assets	388,463	388,284
Total equity	287,557	298,769
Total equity attributable to owners of the company	285,823	297,122
Total equity attributable to owners of the company ratio	73.6%	76.5%
Equity per share attributable to owners of the company (yen)	702.54	729.98

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 *1)

	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)
 - December 31, 2018 : 407,102,254
 - March 31, 2018 : 406,847,515
- [ii] Number of treasury shares at the end of period
 - December 31, 2018 : 7,821
 - March 31, 2018 : 7,411
- [iii] Average number of outstanding shares (during the fiscal year ended December 31)
 - Third quarter ended December 31, 2018: 406,966,797
 - Third quarter ended December 31, 2017: 406,304,134

(Information regarding the implementation of audit procedures)

This financial report is exempt from audit.

(Information regarding presentation currency)

All financial information presented in Japanese yen has been rounded to the nearest million, except when otherwise indicated.

(Caution)

Forecasts in this report are based on the currently available information. Actual results may differ materially depending on a number of factors including adverse economic conditions, delays in new products launch, currency exchange rate, legislative and regulatory developments.

*1(Core basis)

Core results are non-IFRS measures that remove non-core items including amortization on intangible assets associated with products, other income and expenses, finance income and expenses, and temporary expenses of selling, general and administrative expenses in order to provide greater transparency on underlying business performance.

Quarterly consolidated statements of income and comprehensive income

IFRS basis		(JPY millions)
	Nine months ended December 31, 2017	Nine months ended December 31, 2018
Revenue	168,592	173,210
Cost of sales	(66,150)	(69,814)
Gross profit	102,442	103,397
Selling, general and administrative expenses	(49,504)	(51,224)
Research and development expenses	(17,895)	(17,091)
Amortization on intangible assets associated with products	(4,996)	(5,233)
Other income	368	3,929
Other expenses	(327)	(121)
Operating profit	30,087	33,657
Finance income	809	863
Finance expenses	(1,357)	(2,115)
Profit before tax	29,539	32,405
Income tax expenses	(2,192)	(9,037)
Net profit for the period	27,348	23,367
Other comprehensive income		
Items that will not be reclassified subsequently to profit or loss		
Remeasurements of defined benefit plans	—	—
Net gain on financial assets measured at fair value through other comprehensive income	2,854	(2,733)
Items that may be reclassified subsequently to profit or loss		
Foreign currency translation adjustments	4,400	1,098
Other comprehensive income	7,254	(1,635)
Total comprehensive income	34,602	21,732
Profit attributable to		
Owners of the company	27,332	23,376
Non-controlling interests	15	(8)
Net profit for the period	27,348	23,367
Total comprehensive income attributable to		
Owners of the company	34,487	21,819
Non-controlling interests	114	(87)
Total comprehensive income	34,602	21,732
Earnings per share		
Basic earnings per share (yen)	67.27	57.44
Diluted earnings per share (yen)	67.02	57.26

Core basis		(JPY millions)
	Nine months ended December 31, 2017	Nine months ended December 31, 2018
Revenue	168,592	173,210
Core operating profit	35,042	35,082
Core net profit for the period	26,231	25,655
Basic core earnings per share (yen)	64.52	63.06
Diluted core earnings per share (yen)	64.28	62.87
Core profit attributable to		
Owners of the company	26,216	25,663
Non-controlling interests	15	(8)
Core net profit for the period	26,231	25,655

Quarterly consolidated statement of financial position

Assets		(JPY millions)
	March 31, 2018	December 31, 2018
Non-current assets		
Property, plant and equipment	29,706	31,035
Intangible assets	134,495	132,725
Financial assets	35,775	31,730
Deferred tax assets	2,264	2,258
Other non-current assets	2,855	1,685
Total non-current assets	205,095	199,433
Current assets		
Inventories	30,636	31,082
Trade and other receivables	78,654	78,720
Other financial assets	472	256
Other current assets	4,322	3,399
Cash and cash equivalents	69,283	75,394
Total current assets	183,367	188,851
Total assets	388,463	388,284

Equity and liabilities

(JPY millions)

	March 31, 2018	December 31, 2018
Equity		
Equity attributable to owners of the company		
Share capital	8,032	8,186
Capital surplus	8,657	8,714
Treasury shares	(11)	(12)
Retained earnings	249,225	262,404
Other components of equity	19,921	17,830
Total equity attributable to owners of the company	285,823	297,122
Non-controlling interests	1,734	1,647
Total equity	287,557	298,769
Liabilities		
Non-current liabilities		
Financial liabilities	21,244	23,243
Net defined benefit liabilities	1,804	2,240
Provisions	1,367	1,299
Deferred tax liabilities	12,909	12,317
Other non-current liabilities	1,380	1,738
Total non-current liabilities	38,704	40,836
Current liabilities		
Trade and other payables	29,743	27,982
Other financial liabilities	14,404	9,091
Income tax payable	7,656	3,601
Provisions	1,508	641
Other current liabilities	8,890	7,365
Total current liabilities	62,201	48,679
Total liabilities	100,905	89,515
Total equity and liabilities	388,463	388,284

Quarterly consolidated statement of changes in equity

Nine months ended December 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
Balance at April 1, 2016	7,792	8,417	(10)	223,283	—	9,470
Comprehensive income						
Net profit for the period				27,332		
Other comprehensive income						2,854
Total comprehensive income	—	—	—	27,332	—	2,854
Transactions with owners						
Issuance of new shares	119	119				
Acquisition of treasury shares			(1)			
Dividends				(10,563)		
Establishment of subsidiary with non-controlling interests						
Share-based payments						
Other				168		(168)
Total transactions with owners	119	119	(1)	(10,395)	—	(168)
Balance at December 31, 2016	7,911	8,536	(11)	240,220	—	12,156

	Other components of equity			Total equity attributable to owners of the company	Non-controlling interests	Total equity
	Foreign currency translation adjustments	Subscription rights to shares	Total			
Balance at April 1, 2016	5,332	825	15,628	255,110	819	255,929
Comprehensive income						
Net profit for the period			—	27,332	15	27,348
Other comprehensive income	4,301		7,155	7,155	99	7,254
Total comprehensive income	4,301	—	7,155	34,487	114	34,602
Transactions with owners						
Issuance of new shares		(39)	(39)	200		200
Acquisition of treasury shares			—	(1)		(1)
Dividends			—	(10,563)		(10,563)
Establishment of subsidiary with non-controlling interests			—	—	838	838
Share-based payments		218	218	218		218
Other			(168)	—		—
Total transactions with owners	—	179	11	(10,146)	838	(9,308)
Balance at December 31, 2016	9,633	1,004	22,794	279,451	1,772	281,222

Nine months ended December 31, 2018

(JPY millions)

	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity	
					Remeasurements of defined benefit plans	Net gain or loss on financial assets measured at fair value through other comprehensive income
Balance at April 1, 2017	8,032	8,657	(11)	249,225	—	14,364
Comprehensive income						
Net profit for the period				23,376		
Other comprehensive income						(2,733)
Total comprehensive income	—	—	—	23,376	—	(2,733)
Transactions with owners						
Issuance of new shares	87	87				
Acquisition of treasury shares			(1)			
Dividends				(10,581)		
Share-based payments	67	(29)				
Other				385		(385)
Total transactions with owners	154	57	(1)	(10,196)	—	(385)
Balance at December 31, 2017	8,186	8,714	(12)	262,404	—	11,245

	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	4,583	975	19,921	285,823	1,734	287,557
Comprehensive income						
Net profit for the period			—	23,376	(8)	23,367
Other comprehensive income	1,177		(1,557)	(1,557)	(79)	(1,635)
Total comprehensive income	1,177	—	(1,557)	21,819	(87)	21,732
Transactions with owners						
Issuance of new shares		(150)	(150)	23		23
Acquisition of treasury shares			—	(1)		(1)
Dividends			—	(10,581)		(10,581)
Share-based payments			—	38		38
Other			(385)	—		—
Total transactions with owners	—	(150)	(535)	(10,521)	—	(10,521)
Balance at December 31, 2017	5,759	825	17,830	297,122	1,647	298,769

Quarterly consolidated statements of cash flows

(JPY millions)

	Nine months ended December 31, 2017	Nine months ended December 31, 2018
I . Cash flows from operating activities:		
Net profit for the period	27,348	23,367
Depreciation and amortization	8,092	8,223
Impairment losses	168	—
Gain on disposal of non-current assets	—	(3,592)
Finance expense (income)	(158)	(151)
Income tax expenses	2,192	9,037
Decrease (increase) in trade and other receivables	(6,560)	(370)
Decrease (increase) in inventories	2,043	(735)
Increase (decrease) in trade and other payables	617	(1,696)
Increase (decrease) in provisions and net defined benefit liabilities	346	(380)
Other	323	594
Subtotal	34,411	34,297
Interest received	68	154
Dividends received	580	518
Interest paid	(24)	(7)
Income tax paid	(5,990)	(12,268)
Net cash flows from (used in) operating activities	29,045	22,694
II . Cash flows from investing activities:		
Payments for acquisition of investments	(158)	(767)
Proceeds from sales of investments	514	1,025
Payments for acquisition of property, plant and equipment	(3,489)	(4,468)
Proceeds from sale of property, plant and equipment	—	4,338
Payments for acquisition of intangible assets	(3,051)	(2,165)
Other	(18)	(156)
Net cash flows from (used in) investing activities	(6,202)	(2,193)
III . Cash flows from financing activities:		
Proceeds from long-term loans	—	578
Repayments of long-term loans	(6,862)	(4,098)
Capital contribution from non-controlling interests	838	—
Dividends paid	(10,471)	(10,493)
Other	196	20
Net cash flows from (used in) financing activities	(16,299)	(13,993)
IV . Net increase (decrease) in cash and cash equivalents	6,544	6,507
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	1,222	(397)
VII . Cash and cash equivalents at the end of period	60,048	75,394

Revenue of major pharmaceuticals

(JPY millions)

Brand name Generic name/formulation	Therapeutic category	Region	Year ended March 31, 2018				Year ending March 31, 2019			
			Nine months ended December 31, 2017 Actual	Changes from same period of previous year	Year ended March 31 Actual	Changes from same period of previous year	Nine months ended December 31, 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	11,434	12.8%	14,944	16.0%	11,513	0.7%	15,443	3.3%
		Japan	3,369	(11.3%)	4,105	(11.9%)	2,569	(23.7%)	3,415	(16.8%)
		Asia	6,820	26.8%	9,225	32.2%	7,794	14.3%	10,154	10.1%
		EMEA	1,245	29.6%	1,614	29.7%	1,150	(7.7%)	1,874	16.1%
Tarivid ofloxacin/ophthalmic solution	Bacterial conjunctivitis	Total	1,246	(5.1%)	1,581	2.6%	1,129	(9.4%)	1,507	(4.7%)
		Japan	414	(9.2%)	508	(9.2%)	390	(6.0%)	458	(9.8%)
		Asia	832	(3.0%)	1,073	9.3%	740	(11.1%)	1,049	(2.2%)
Tapcom tafluprost-timolol maleate/ combination ophthalmic solution	Glaucoma	Total	2,966	42.1%	3,892	39.1%	3,612	21.8%	4,950	27.2%
		Japan	1,953	10.9%	2,479	9.9%	2,002	2.5%	2,454	(1.0%)
		Asia	109	438.5%	158	317.6%	221	102.3%	289	82.7%
		EMEA	904	195.1%	1,255	148.8%	1,389	53.7%	2,208	75.9%
Tapros tafluprost/ophthalmic solution	Glaucoma	Total	13,791	7.9%	17,844	8.8%	13,942	1.1%	18,883	5.8%
		Japan	7,590	(0.2%)	9,610	0.2%	7,526	(0.8%)	9,686	0.8%
		Asia	1,343	36.6%	1,807	47.3%	1,571	16.9%	2,026	12.1%
		EMEA	4,857	15.9%	6,427	15.0%	4,846	(0.2%)	7,171	11.6%
Cosopt dorzolamide hydrochloride- timolol maleate/combination ophthalmic solution	Glaucoma	Total	18,622	9.4%	24,200	9.2%	16,956	(8.9%)	21,202	(12.4%)
		Japan	9,057	0.7%	11,403	0.3%	7,247	(20.0%)	8,957	(21.4%)
		Asia	2,440	30.1%	3,197	19.8%	2,769	13.5%	3,317	3.8%
		EMEA	7,125	15.9%	9,600	18.1%	6,939	(2.6%)	8,928	(7.0%)
Timoptol timolol maleate/ ophthalmic solution	Glaucoma	Total	1,183	1.3%	1,451	(3.8%)	780	(34.1%)	990	(31.8%)
		Japan	662	(16.0%)	787	(18.7%)	398	(39.9%)	470	(40.3%)
		Asia	86	(4.3%)	116	(2.7%)	88	2.1%	112	(3.3%)
		EMEA	435	50.0%	548	30.1%	295	(32.3%)	408	(25.6%)
Timoptol XE timolol maleate/ long-acting ophthalmic solution	Glaucoma	Total	1,766	(6.6%)	2,221	(6.8%)	1,485	(15.9%)	1,976	(11.0%)
		Japan	1,144	(12.2%)	1,407	(12.9%)	922	(19.4%)	1,203	(14.5%)
		Asia	79	20.1%	105	19.1%	82	4.1%	109	3.6%
		EMEA	544	4.2%	709	4.4%	481	(11.6%)	664	(6.3%)
Trusopt dorzolamide hydrochloride/ ophthalmic solution	Glaucoma	Total	3,587	7.3%	4,677	7.7%	3,436	(4.2%)	4,547	(2.8%)
		Japan	1,325	(4.2%)	1,641	(5.2%)	1,175	(11.3%)	1,446	(11.9%)
		Asia	232	11.8%	327	20.9%	300	29.7%	462	41.3%
		EMEA	2,031	15.9%	2,709	15.7%	1,961	(3.5%)	2,639	(2.6%)
Rescula isopropyl unoprostone/ ophthalmic solution	Glaucoma	Total	1,200	(9.2%)	1,467	(10.1%)	964	(19.6%)	1,256	(14.4%)
		Japan	1,200	(9.2%)	1,467	(10.1%)	964	(19.6%)	1,256	(14.4%)
Alesion epinastine hydrochloride/ ophthalmic solution	Allergy	Total	7,515	19.4%	16,851	37.7%	7,703	2.5%	17,727	5.2%
		Japan	7,515	19.4%	16,851	37.7%	7,703	2.5%	17,727	5.2%
Flumetholone fluorometholone/ ophthalmic solution	Inflammation	Total	2,604	3.4%	3,497	4.5%	2,399	(7.9%)	3,141	(10.2%)
		Japan	1,566	(4.6%)	2,113	(5.0%)	1,132	(27.7%)	1,652	(21.8%)
		Asia	1,038	18.2%	1,385	23.2%	1,267	22.0%	1,490	7.6%
Kary Uni pirenoxine/ ophthalmic solution	Senile cataract	Total	3,518	9.0%	4,413	7.0%	3,199	(9.1%)	4,398	(0.3%)
		Japan	2,187	(3.7%)	2,741	(3.2%)	2,069	(5.4%)	2,644	(3.6%)
		Asia	1,331	39.0%	1,672	29.6%	1,130	(15.1%)	1,755	4.9%
Oftan Catachrom cytochrome C, adenosine, nicotinamide/ ophthalmic solution	Senile cataract	Total	2,186	66.6%	2,695	21.2%	1,946	(11.0%)	2,800	3.9%
		EMEA	2,186	66.6%	2,695	21.2%	1,946	(11.0%)	2,800	3.9%
Opegan Hi sodium hyaluronate/ adjuvant for ophthalmic operations	Adjuvant for ophthalmic operations	Total	1,830	1.8%	2,304	0.8%	1,683	(8.1%)	2,109	(8.5%)
		Japan	1,830	1.8%	2,304	0.8%	1,683	(8.1%)	2,109	(8.5%)
Eylea * aflibercept/ solution for intravitreal injection	Intravitreal VEGF inhibitor	Total	40,010	13.1%	51,517	14.1%	43,790	9.4%	54,473	5.7%
		Japan	40,010	13.1%	51,517	14.1%	43,790	9.4%	54,473	5.7%
Hyalein sodium hyaluronate/ophthalmic solution	Dry eye	Total	14,124	1.6%	18,170	3.3%	14,943	5.8%	17,708	(2.5%)
		Japan	8,692	(8.8%)	10,772	(9.1%)	6,939	(20.2%)	8,541	(20.7%)
		Asia	5,432	24.4%	7,397	28.8%	8,004	47.3%	9,167	23.9%
Diquas diquafosol sodium/ophthalmic solution	Dry eye	Total	11,028	20.7%	14,286	19.6%	11,762	6.7%	16,087	12.6%
		Japan	9,937	17.0%	12,822	16.4%	10,784	8.5%	14,463	12.8%
		Asia	1,091	69.6%	1,463	58.3%	978	(10.4%)	1,625	11.0%
Ikervis ciclosporin/ophthalmic solution	Dry eye	Total	1,661	99.2%	2,049	57.2%	2,415	45.4%	2,990	45.9%
		Asia	4	274.2%	68	—	324	—	437	537.6%
		EMEA	1,657	99.0%	1,981	52.2%	2,091	26.2%	2,553	28.9%
Cationorm	Dry eye	Total	1,638	26.8%	2,092	14.0%	1,873	14.3%	3,196	52.8%
		Asia	176	104.0%	199	72.3%	118	(32.8%)	173	(13.2%)
		EMEA	1,267	20.0%	1,670	16.1%	1,503	18.7%	2,713	62.5%
		US	195	30.1%	223	(20.4%)	251	28.8%	310	38.8%
OTC pharmaceuticals		Total	11,618	21.6%	14,594	16.3%	11,230	(3.3%)	16,498	13.0%
		Japan	11,412	20.6%	14,301	15.1%	11,014	(3.5%)	16,144	12.9%
		Asia	207	127.9%	293	121.8%	216	4.7%	355	20.8%

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

Exchange rate (yen)	Major currency	3rd quarter ended December 31, 2017	Fiscal year ended March 31, 2018	3rd quarter ended December 31, 2018	Fiscal year to March 31, 2019(Forecasts)
	US dollar	111.75	110.94	111.15	110.00
	Euro	128.90	129.92	129.51	130.00
	CNY	16.64	16.84	16.57	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 February 5

■ 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. Started an additional Phase 3 in December 2018 and planning to complete in January ~ June 2021 in the U.S. NDA filed in April 2015 in Asia.										

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 AGC	China						
A fixed dose combination drug of a prostaglandin F2α derivative and a beta-adrenergic receptor blocker. Launched in Japan in November 2014. Launched successively in European countries since January 2015. Launched successively in Asian countries since April 2016. Started Phase 3 in January 2019 and planning to complete in the 1st half of FY2020 in China.										

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 H ₁ receptor antagonist with membrane-stabilizing function, as treatment for allergic conjunctivitis. High dose drug. Filed for manufacturing and marketing approval in September 2018 and planning to receive approval in July ~ December 2019 in Japan.										

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						Nov-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. Launched in November 2018 in Japan. 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-endothelial antibody. Started Phase 2a in July 2017 and planning to complete in the 2nd half of FY2019 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 aims to reduce juvenile myopia progression. Started Phase 2 in November 2017 and planning to complete in the 2nd half of FY2019 in Asia.										

—	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
—	DE-128 <i>(MicroShunt)</i>	Glaucoma	Original	U.S.	(Phase 2/3)					
				Europe						
In August 2016, Santen acquired InnFocus, developer of MicroShunt, a drainage implant device designed to lower and sustain intraocular pressure (IOP) for the treatment of primary open-angle glaucoma through the drainage of aqueous humor. Conducting Phase 2/3 in the U.S. and Europe in advance of application to FDA. Planning to complete PMA rolling submission in 2019 and launch in 2020 in U.S. Received CE Mark in Europe.										

Generic name	Dev.code	Indication	Original/Licensor	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 penetration. 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. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
ciclosporin	DE-076C (Vekacia)	Vernal keratoconjunctivitis	Original	Europe	Oct-2018					
				Asia	Nov-2018					
				Others	Dec-2018					
An ophthalmic emulsion which improves vernal keratoconjunctivitis by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue penetration. Received the Marketing Authorization Application approval from the European Commission Agency in July 2018 and launched in October 2018 in U.K. Filed for manufacturing and marketing approval in November 2018 and planning to receive approval in July ~ December 2019 in Asia. Received marketing approval in December 2018 and planning to launch in 2019 in Canada.										

Generic name	Dev. code	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 F _{2α} derivative, for the treatment of glaucoma and ocular hypertension.										

■ Changes from Q2 FY18 (November 7, 2018)

Dev. code	Changes
DE-109	Started an additional Phase 3 in December 2018 in the U.S.
DE-111	Started Phase 3 in January 2019 in China.
DE-117	Launched in November 2018 in Japan.
DE-076C (Vekacia)	Filed in November 2018 in Asia and received marketing approval in December 2018 in Canada.

Other consolidated information

Capital expenditures

(JPY millions)

	Nine months ended December 31, 2017	Year ended March 31, 2018	Nine months ended December 31, 2018	Year ending March 31, 2019
	Actual			Forecast
Consolidated	4,460	5,445	5,072	9,000

Depreciation and amortization

(JPY millions)

	Nine months ended December 31, 2017	Year ended March 31, 2018	Nine months ended December 31, 2018	Year ending March 31, 2019
	Actual			Forecast
Manufacturing cost	1,445	1,950	1,397	2,040
Selling, general and administrative expenses	1,076	1,453	1,105	1,520
R&D expenses	574	752	489	700
Consolidated total	3,095	4,155	2,991	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)

	Nine months ended December 31, 2017	Year ended March 31, 2018	Nine months ended December 31, 2018	Year ending March 31, 2019
	Actual			Forecast
Intangible assets (Merck products)	4,140	5,592	4,356	5,810
Intangible assets (Ikervis)	548	736	550	740
Other	308	412	327	380
Consolidated total	4,996	6,740	5,233	6,930

Research & Development expenses

(JPY millions)

	Nine months ended December 31, 2017	Year ended March 31, 2018	Nine months ended December 31, 2018	Year ending March 31, 2019
	Actual			Forecast
Consolidated	17,895	24,398	17,091	25,000
Percent of revenue	10.6%	10.8%	9.9%	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.