

Press Release



Santen Reports Consolidated Results for Q2 Fiscal 2019

November 6, 2019 – Santen Pharmaceutical Co., Ltd. (Osaka, JAPAN, Tokyo Stock Exchange Code 4536) (Santen) today announced consolidated performance for Q2 FY19, the cumulative six month period ended September 30, 2019.

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 FY19 reached 118.8 billion yen, an increase of 3.9% year-on-year. In the mainstay prescription pharmaceuticals business, sales in Japan increased 2.2% year on year. In EMEA (Europe, the Middle East and Africa), China and Asia, our products are steadily penetrating the market. Growth in sales in each area was maintained at 2.3%, 17.1%, and 6.0%, respectively, in yen terms. Operating profit on a core basis rose ¥1.5 billion yen, or 6.2%, due to the optimization of selling, general and administrative (SG&A) expenses and R&D expenses.

The results for Q2 FY19 are generally as planned, and there are no changes from the forecasts for the current fiscal year ending March 31, 2020, announced on May 9, 2019.

The annual dividend forecast has been revised to 27 yen, an increase of 1 yen from the previous forecast.

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 FY19** actual (JPY millions)	change (YoY%)	FY19 forecast (JPY millions)	change (YoY%)
Revenue	118,775	+3.9%	248,000	+6.0%
Core operating profit	25,639	+6.2%	51,000	+5.7%
Core net profit for the period	18,794	+5.6%	37,700	+4.5%
Earnings per share (basic)	47.14		95.29	

IFRS	Q2 FY19** actual (JPY millions)	change (YoY%)	FY19 forecast (JPY millions)	change (YoY%)
Revenue	118,775	+3.9%	248,000	+6.0%
Operating profit	19,011	(8.7%)	34,500	(23.5%)
Net profit for the period	13,129	(8.7%)	23,200	(27.4%)

* 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, 2019.

Additional Santen investor relations information can be found here: <https://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.

Contact

Kaori (Kate) Itagaki, Investor Relations Group, Santen Pharmaceutical Co., Ltd.

E-mail: ir@santen.com, Tel: +81-6-4802-9360

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, 2019

(1) Operating results (Core basis)

	Six months ended September 30, 2018	Six months ended September 30, 2019	% change
Revenue	114,344	118,775	+3.9%
Core operating profit	24,135	25,639	+6.2%
Core net profit for the period	17,799	18,794	+5.6%
Core net profit for the period attributable to owners of the company	17,803	18,814	+5.7%
Basic core earnings per share (yen)	43.75	47.14	
Diluted core earnings per share (yen)	43.62	47.00	

(IFRS)

	Six months ended September 30, 2018	Six months ended September 30, 2019	% change
Revenue	114,344	118,775	+3.9%
Operating profit	20,825	19,011	(8.7%)
Profit before tax	19,790	18,408	(7.0%)
Net profit for the period	14,376	13,129	(8.7%)
Net profit for the period attributable to owners of the company	14,380	13,148	(8.6%)
Total comprehensive income for the period	22,294	7,725	(65.4%)
Basic earnings per share (yen)	35.34	32.94	
Diluted earnings per share (yen)	35.23	32.85	

(2) Financial position

	March 31, 2019	September 30, 2019
Total assets	391,186	397,073
Total equity	292,572	295,192
Total equity attributable to owners of the company	290,900	293,662
Total equity attributable to owners of the company ratio	74.4%	74.0%
Equity per share attributable to owners of the company (yen)	728.97	735.77

2. Dividends

	Year to March 2019	Year to March 2020	(Forecasts) Year to March 2020
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	—	14.00
Annual dividends per share (yen)	26.00	—	27.00

3. Consolidated forecasts of results for the year ending March 31, 2020

(Core basis)

	Year to March 2020	% change
Revenue	248,000	+6.0%
Core operating profit	51,000	+5.7%
Core net profit for the year	37,700	+4.5%
Basic core earnings per share (yen)	95.29	

(IFRS)

	Year to March 2020	% change
Revenue	248,000	+6.0%
Operating profit	34,500	(23.5%)
Profit before tax	34,300	(20.4%)
Net profit for the year	23,200	(27.4%)
Basic earnings per share (yen)	58.98	

***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, 2019: 399,850,954
 - March 31, 2019 : 399,782,354
- [ii] Number of treasury shares at the end of period
 - September 30, 2019: 597,000
 - March 31, 2019 : 663,412
- [iii] Average number of outstanding shares (during the fiscal year ended September 30)
 - Second quarter ended September 30, 2019: 399,107,321
 - Second quarter ended September 30, 2018: 406,937,690

(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	(JPY millions)	
	Six months ended September 30, 2018	Six months ended September 30, 2019
Revenue	114,344	118,775
Cost of sales	(45,772)	(48,302)
Gross profit	68,573	70,473
Selling, general and administrative expenses	(33,474)	(33,422)
Research and development expenses	(10,964)	(11,412)
Amortization on intangible assets associated with products	(3,473)	(4,937)
Other income	259	160
Other expenses	(96)	(1,851)
Operating profit	20,825	19,011
Finance income	547	518
Finance expenses	(1,581)	(1,121)
Profit before tax	19,790	18,408
Income tax expenses	(5,414)	(5,279)
Net profit for the period	14,376	13,129
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	3,907	(747)
Items that may be reclassified subsequently to profit or loss		
Foreign currency translation adjustments	4,011	(4,658)
Other comprehensive income	7,918	(5,404)
Total comprehensive income	22,294	7,725
Profit attributable to		
Owners of the company	14,380	13,148
Non-controlling interests	(4)	(19)
Net profit for the period	14,376	13,129
Total comprehensive income attributable to		
Owners of the company	22,345	7,866
Non-controlling interests	(51)	(142)
Total comprehensive income	22,294	7,725
Earnings per share		
Basic earnings per share (yen)	35.34	32.94
Diluted earnings per share (yen)	35.23	32.85

Core basis (JPY millions)

	Six months ended September 30, 2018	Six months ended September 30, 2019
Revenue	114,344	118,775
Core operating profit	24,135	25,639
Core net profit for the period	17,799	18,794
Basic core earnings per share (yen)	43.75	47.14
Diluted core earnings per share (yen)	43.62	47.00
Core profit attributable to		
Owners of the company	17,803	18,814
Non-controlling interests	(4)	(19)
Core net profit for the period	17,799	18,794

Quarterly consolidated statement of financial position

Assets		(JPY millions)
	March 31, 2019	September 30, 2019
Non-current assets		
Property, plant and equipment	31,699	38,291
Intangible assets	131,110	125,090
Financial assets	30,044	27,388
Deferred tax assets	1,771	1,991
Other non-current assets	1,819	1,886
Total non-current assets	196,444	194,645
Current assets		
Inventories	35,235	33,652
Trade and other receivables	84,618	78,342
Other financial assets	267	429
Other current assets	3,826	5,033
Cash and cash equivalents	70,796	84,972
Total current assets	194,742	202,428
Total assets	391,186	397,073

Equity and liabilities

(JPY millions)

	March 31, 2019	September 30, 2019
Equity		
Equity attributable to owners of the company		
Share capital	8,252	8,287
Capital surplus	8,661	8,631
Treasury shares	(1,131)	(1,011)
Retained earnings	258,659	267,452
Other components of equity	16,461	10,303
Total equity attributable to owners of the company	290,900	293,662
Non-controlling interests	1,672	1,530
Total equity	292,572	295,192
Liabilities		
Non-current liabilities		
Financial liabilities	23,520	30,296
Net defined benefit liabilities	1,992	2,325
Provisions	1,255	600
Deferred tax liabilities	9,389	7,746
Other non-current liabilities	1,795	1,332
Total non-current liabilities	37,951	42,298
Current liabilities		
Trade and other payables	32,079	31,411
Other financial liabilities	12,116	14,010
Income tax payable	7,185	6,270
Provisions	717	474
Other current liabilities	8,566	7,417
Total current liabilities	60,663	59,583
Total liabilities	98,614	101,881
Total equity and liabilities	391,186	397,073

Quarterly consolidated statement of changes in equity

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	—	—	—	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	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

Six months ended September 30, 2019

(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, 2019	8,252	8,661	(1,131)	258,659	—	10,230
Comprehensive income						
Net profit for the period				13,148		
Other comprehensive income						(747)
Total comprehensive income	—	—	—	13,148	—	(747)
Transactions with owners						
Issuance of new shares	35	35				
Acquisition of treasury shares			(0)			
Disposals of treasury shares		(112)	121			
Dividends				(5,189)		
Share-based payments		47				
Other				833		(833)
Total transactions with owners	35	(30)	121	(4,356)	—	(833)
Balance at September 30, 2019	8,287	8,631	(1,011)	267,452	—	8,651

(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, 2019	5,428	802	16,461	290,900	1,672	292,572
Comprehensive income						
Net profit for the period			—	13,148	(19)	13,129
Other comprehensive income	(4,535)		(5,282)	(5,282)	(122)	(5,404)
Total comprehensive income	(4,535)	—	(5,282)	7,866	(142)	7,725
Transactions with owners						
Issuance of new shares		(43)	(43)	28		28
Acquisition of treasury shares			—	(0)		(0)
Disposals of treasury shares			—	9		9
Dividends			—	(5,189)		(5,189)
Share-based payments			—	47		47
Other			(833)	—		—
Total transactions with owners	—	(43)	(876)	(5,105)	—	(5,105)
Balance at September 30, 2019	893	760	10,303	293,662	1,530	295,192

Quarterly consolidated statements of cash flows

(JPY millions)

	Six months ended September 30, 2018	Six months ended September 30, 2019
I . Cash flows from operating activities:		
Net profit for the period	14,376	13,129
Depreciation and amortization	5,510	8,202
Finance expenses (income)	(11)	(268)
Income tax expenses	5,414	5,279
Decrease (increase) in trade and other receivables	2,477	5,449
Decrease (increase) in inventories	(1,158)	558
Increase (decrease) in trade and other payables	(1,341)	(864)
Increase (decrease) in provisions and net defined benefit liabilities	(445)	(474)
Other	(338)	(226)
Subtotal	24,486	30,786
Interest received	103	52
Dividends received	259	260
Interest paid	(6)	(92)
Income tax paid	(7,594)	(7,419)
Net cash flows from (used in) operating activities	17,249	23,588
II . Cash flows from investing activities:		
Payments for acquisition of investments	(210)	(121)
Proceeds from sales of investments	—	1,671
Payments for acquisition of property, plant and equipment	(2,863)	(2,792)
Payments for acquisition of intangible assets	(750)	(1,633)
Other	(147)	967
Net cash flows from (used in) investing activities	(3,971)	(1,908)
III . Cash flows from financing activities:		
Proceeds from long-term loans	245	588
Repayments of long-term loans	(2,908)	—
Dividends paid	(5,288)	(5,182)
Repayments of lease obligations	(2)	(1,396)
Other	23	28
Net cash flows from (used in) financing activities	(7,930)	(5,962)
IV . Net increase (decrease) in cash and cash equivalents	5,348	15,717
V . Cash and cash equivalents at the beginning of period	69,283	70,796
VI . Effect of exchange rate changes on cash and cash equivalents	606	(1,542)
VII . Cash and cash equivalents at the end of period	75,237	84,972

Revenue of major products

(JPY millions)

Brand name Generic name/formulation	Therapeutic category	Region	Year ended March 31, 2019				Year ending March 31, 2020			
			Six months ended September 30, 2018 Actual	Changes from same period of previous year	Year ended March 31, 2019 Actual	Changes from same period of previous year	Six months ended September 30, 2019 Actual	Changes from same period of previous year	Year ending March 31, 2020 Forecasts**	Changes from same period of previous year
Cravit levofloxacin/ophthalmic solution	Bacterial conjunctivitis	Total	8,076	5.4%	15,028	0.6%	8,997	11.4%	15,733	4.7%
		Japan	1,754	(24.3%)	3,175	(22.7%)	1,430	(18.5%)	2,528	(20.4%)
		China	4,830	22.9%	8,860	10.9%	5,953	23.3%	9,924	12.0%
		Asia	725	15.1%	1,524	23.5%	855	18.0%	1,873	22.9%
		EMEA	766	(1.7%)	1,468	(9.0%)	757	(1.2%)	1,407	(4.2%)
Tarivid ofloxacin/ophthalmic solution	Bacterial conjunctivitis	Total	795	(9.9%)	1,445	(8.6%)	781	(1.7%)	1,472	1.9%
		Japan	266	(6.1%)	482	(5.2%)	230	(13.4%)	364	(24.5%)
		China	345	(8.5%)	599	(13.8%)	363	5.2%	581	(3.0%)
		Asia	184	(17.2%)	364	(3.7%)	188	2.2%	527	44.9%
Tapcom tafluprost-timolol maleate/ combination ophthalmic solution	Glaucoma	Total	2,307	23.0%	4,788	23.0%	2,613	13.3%	5,708	19.2%
		Japan	1,282	1.3%	2,549	2.8%	1,286	0.3%	2,724	6.9%
		Asia	142	122.8%	308	94.9%	186	30.7%	400	29.7%
		EMEA	883	61.6%	1,930	53.9%	1,142	29.2%	2,583	33.8%
Tapros tafluprost/ophthalmic solution	Glaucoma	Total	9,094	1.5%	18,014	1.0%	9,025	(0.8%)	18,645	3.5%
		Japan	4,828	(2.2%)	9,554	(0.6%)	4,712	(2.4%)	9,135	(4.4%)
		China	89	63.7%	228	54.8%	165	86.1%	370	62.3%
		Asia	954	15.6%	1,857	11.9%	961	0.7%	1,992	7.2%
		EMEA	3,223	2.5%	6,375	(0.8%)	3,186	(1.1%)	7,149	12.1%
Cosopt dorzolamide hydrochloride-timolol maleate/comboination ophthalmic solution	Glaucoma	Total	11,473	(5.7%)	21,985	(9.2%)	10,462	(8.8%)	20,341	(7.5%)
		Japan	4,933	(16.6%)	8,919	(21.8%)	3,792	(23.1%)	7,608	(14.7%)
		Asia	1,801	13.8%	3,675	14.9%	2,033	12.9%	3,745	1.9%
		EMEA	4,739	1.6%	9,392	(2.2%)	4,637	(2.1%)	8,988	(4.3%)
Timoptol timolol maleate/ ophthalmic solution (* Including Timoptol XE)	Glaucoma	Total	1,510	(22.4%)	2,874	(21.7%)	1,284	(15.0%)	2,756	(4.1%)
		Japan	879	(26.2%)	1,645	(25.0%)	711	(19.1%)	1,561	(5.1%)
		Asia	109	(2.7%)	221	(0.2%)	117	8.2%	231	4.7%
		EMEA	523	(18.7%)	1,008	(19.8%)	456	(12.8%)	963	(4.4%)
Trusopt dorzolamide hydrochloride/ ophthalmic solution	Glaucoma	Total	2,293	0.8%	4,586	(1.9%)	2,279	(0.6%)	4,530	(1.2%)
		Japan	769	(11.2%)	1,474	(10.2%)	702	(8.7%)	1,359	(7.8%)
		Asia	198	30.3%	415	26.9%	228	14.9%	526	26.6%
		EMEA	1,327	5.4%	2,697	(0.4%)	1,349	1.7%	2,645	(1.9%)
EYBELIS Omidenepeg Isopropyl/ ophthalmic solution	Glaucoma	Total	—	—	431	—	637	—	2,366	449.0%
		Japan	—	—	431	—	637	—	2,366	449.0%
Alesion epinastine hydrochloride/ ophthalmic solution	Allergy	Total	4,893	(3.8%)	19,445	15.4%	4,933	0.8%	21,865	12.4%
		Japan	4,893	(3.8%)	19,445	15.4%	4,933	0.8%	21,865	12.4%
Flumetholon fluorometholone/ ophthalmic solution	Inflammation	Total	1,747	(5.2%)	3,302	(5.6%)	1,786	2.2%	3,293	(0.3%)
		Japan	769	(27.4%)	1,640	(22.4%)	624	(18.8%)	1,432	(12.7%)
		China	747	22.1%	1,231	16.2%	827	10.7%	1,309	6.3%
		Asia	231	34.1%	430	32.6%	335	45.1%	552	28.3%
Kary Uni pirenoxine/ ophthalmic solution	Senile cataract	Total	2,117	(12.8%)	4,076	(7.6%)	2,110	(0.3%)	4,122	1.1%
		Japan	1,343	(7.1%)	2,604	(5.0%)	1,327	(1.1%)	2,597	(0.2%)
		China	422	(14.1%)	760	(14.1%)	370	(12.2%)	756	(0.5%)
		Asia	352	(28.3%)	713	(9.5%)	413	17.3%	768	7.8%
Oftan Catachrom cytochrome C, adenosine, nicotinamide/ ophthalmic solution	Senile cataract	Total	1,177	(18.7%)	2,397	(11.1%)	1,233	4.7%	2,445	2.0%
		EMEA	1,177	(18.7%)	2,397	(11.1%)	1,233	4.7%	2,445	2.0%
Opegan Hi sodium hyaluronate/ adjuvant for ophthalmic operations	Adjuvant for ophthalmic operations	Total	1,065	(10.7%)	2,154	(6.5%)	1,183	11.2%	2,011	(6.7%)
		Japan	1,065	(10.7%)	2,154	(6.5%)	1,183	11.2%	2,011	(6.7%)
Eylea * aflibercept/ solution for intravitreal injection	Intravitreal VEGF inhibitor	Total	28,020	7.6%	56,157	9.0%	30,750	9.7%	58,363	3.9%
		Japan	28,020	7.6%	56,157	9.0%	30,750	9.7%	58,363	3.9%
Hyalain sodium hyaluronate/ophthalmic solution	Dry eye	Total	10,445	10.5%	18,902	4.0%	10,070	(3.6%)	19,207	1.6%
		Japan	4,518	(21.3%)	8,763	(18.7%)	4,111	(9.0%)	7,152	(18.4%)
		China	4,083	41.6%	7,567	31.3%	4,872	19.3%	9,792	29.4%
		Asia	1,844	121.8%	2,572	57.3%	1,086	(41.1%)	2,263	(12.0%)
Diquas diqafosol sodium/ophthalmic solution	Dry eye	Total	7,679	7.0%	15,367	7.6%	9,016	17.4%	16,866	9.8%
		Japan	6,963	8.0%	13,932	8.7%	7,773	11.6%	15,082	8.3%
		China	—	—	25	—	81	—	235	829.7%
		Asia	716	(2.2%)	1,409	(3.7%)	1,162	62.3%	1,549	10.0%
Ikervis ciclosporin/ophthalmic solution	Dry eye	Total	1,561	54.2%	3,391	65.5%	1,771	13.5%	4,091	20.7%
		Asia	195	—	459	570.3%	360	84.4%	917	99.7%
		EMEA	1,366	35.1%	2,932	48.0%	1,412	3.4%	3,174	8.3%
Cationorm	Dry eye	Total	1,153	22.9%	2,512	20.1%	1,588	37.7%	3,486	38.7%
		Japan	79	(9.9%)	168	(15.8%)	121	51.9%	322	91.8%
		EMEA	977	22.5%	1,989	19.1%	1,008	3.2%	2,634	32.4%
		North America	97	84.4%	355	59.1%	460	375.9%	530	49.1%
LENTIS Comfort	Intraocular lens for cataract treatment	Total	—	—	129	—	474	—	2,910	—
		Japan	—	—	129	—	474	—	2,910	—
OTC pharmaceuticals		Total	7,566	(1.9%)	14,223	(2.5%)	6,710	(11.3%)	15,128	6.4%
		Japan	7,418	(1.9%)	13,930	(2.6%)	6,556	(11.6%)	14,707	5.6%
		Asia	148	(3.4%)	293	(0.1%)	154	4.0%	421	43.5%

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

**Original exchange rates as of May 9th, 2019 are applied to Forecasts.

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 October 2019

■ Pipeline development status (clinical stage)

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 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 F _{2α} 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 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-2019	
An H ₁ receptor antagonist with membrane-stabilizing function, as treatment for allergic conjunctivitis. High dose drug. Received manufacturing and marketing approval in September 2019 in Japan.										

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
omidenepag isopropyl	DE-117	Glaucoma/ Ocular hypertension	Co-development with Ube Industries	U.S.						
				Japan	Nov-2018					
				Asia	Apr-2019					
An EP2 receptor agonist with a new mechanism of action. Started Phase 3 in September 2018 in the U.S. Launched in November 2018 in Japan. Filed for marketing approval in April 2019 in Korea with successive filings in Asian countries.										

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 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/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
atropine sulfate	DE-127	Myopia	Singapore Health Services, Nanyang Technological University	Japan	(Phase 2/3)					
				Asia						
Muscarinic antagonist which reduces juvenile myopia progression. Started Phase 2/3 in August 2019 in Japan. Started Phase 2 in November 2017 in Asia.										

—	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
glaucoma implant device	DE-128	Glaucoma	Original	U.S.	(Phase 2/3)					
				Europe						
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 in the U.S. Received CE Mark in Europe.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
ciclosporin	DE-076C (Vekacia)	Vernal keratoconjunctivitis	Original	Europe	Oct-2018					
				Asia	Aug-2019					
				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. Received approval of expanded indication to Ikervis in August 2019 in Taiwan. Received marketing approval in December 2018 in Canada.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
latanoprost	DE-130A (Catioprost)	Glaucoma/ Ocular hypertension	Original	Europe						
				Asia						
An ophthalmic emulsion of a prostaglandin F _{2α} derivative, for the treatment of glaucoma and ocular hypertension. Started Phase 3 in April 2019 in Europe and Asia.										

—	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	NDA Filed	Approved	Launched
intraocular lens	MD-16	Cataract	Oculentis	Japan				May-2019		
A toric intraocular lens for correcting astigmatism, which be implanted into an aphakia after cataract surgery. Filed for manufacturing and marketing approval in May 2019 in Japan.										

■ Changes from Q1 FY19 (August 1, 2019)

Dev. code	Changes
DE-114A	Received manufacturing and marketing approval in September 2019 in Japan.
DE-127	Started Phase 2/3 in August 2019 in Japan.
DE-067C	Received marketing approval in August 2019 in Taiwan.

Other consolidated information

Capital expenditures

(JPY millions)

	Six months ended September 30, 2018	Year ended March 31, 2019	Six months ended September 30, 2019	Year ending March 31, 2020
	Actual			Forecast
Consolidated	3,233	7,220	4,694	10,000

Note: Excluding the increase for the right-of-use asset.

Depreciation and amortization

(JPY millions)

	Six months ended September 30, 2018	Year ended March 31, 2019	Six months ended September 30, 2019	Year ending March 31, 2020
	Actual			Forecast
Manufacturing cost	946	1,872	1,049	2,140
Selling, general and administrative expenses	765	1,478	727	1,860
R&D expenses	326	631	322	760
Consolidated total	2,037	3,981	2,098	4,760

Note: Excluding amortization on intangible assets associated with products, long-term advance expense and the right-of-use asset.

Amortization on intangible assets associated with products

(JPY millions)

	Six months ended September 30, 2018	Year ended March 31, 2019	Six months ended September 30, 2019	Year ending March 31, 2020
	Actual			Forecast
Intangible assets (Merck products)	2,904	5,808	2,904	5,810
Intangible assets (DE-128*)	--	--	1,394	2,830
Intangible assets (Ikervis)	368	727	343	740
Other	201	453	295	520
Consolidated total	3,473	6,988	4,937	9,900

* DE-128 (PRESERFLO MicroShunt)

Research and Development expenses

(JPY millions)

	Six months ended September 30, 2018	Year ended March 31, 2019	Six months ended September 30, 2019	Year ending March 31, 2020
	Actual			Forecast
Consolidated	10,964	23,759	11,412	28,000
Percent of revenue	9.6%	10.2%	9.6%	11.3%

Exchange rate

(yen)

Major currency	2nd quarter ended September 30, 2018	Fiscal year ended March 31, 2019	2nd quarter ended September 30, 2019	Fiscal year to March 31, 2020(Forecasts)
USD	110.21	110.82	108.82	110.00
EUR	129.81	128.38	121.28	120.00
CNY	16.70	16.52	15.77	16.00

*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.