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February 3, 2015

SANTEN PHARMACEUTICAL CO., LTD.

Code : 4536

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

Third Quarter Financial Results for the Fiscal Year Ending March 31, 2015 [Japan GAAP] (Consolidated)

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(Figures are rounded down to the nearest million yen)

1. Consolidated Performance for the nine months ended December 31, 2014

(1) Operating results

(Percentage figures represent changes from same period of previous year.)

	Nine months ended December 31, 2014	Nine months ended December 31, 2013	% change
Net sales (millions of yen)	116,842	108,946	+7.2%
Operating income (millions of yen)	24,337	23,633	+3.0%
Ordinary income (millions of yen)	24,811	24,297	+2.1%
Net income (millions of yen)	16,190	15,376	+5.3%
Net income per share (yen)	196.01	186.32	
Diluted net income per share (yen)	195.20	185.74	

Note : Comprehensive income :

Third quarter ended December 31, 2014 : ¥ 22,279 million (-1.7%)

Third quarter ended December 31, 2013 : ¥ 22,656 million (+62.9%)

(2) Financial condition

	December 31, 2014	March 31, 2014
Total assets (millions of yen)	278,020	231,105
Net assets (millions of yen)	195,515	181,209
Equity ratio	70.1%	78.2%
Net assets per share (yen)	2,359.70	2,189.50

Reference : Equity (Consolidated) :

Third quarter ended December 31, 2014 : ¥ 194,948 million

Fiscal year ended March 31, 2014 : ¥ 180,810 million

2. Dividends

	Year to March 2015	(Forecasts) Year to March 2015	Year to March 2014
First quarter dividends per share (yen)	—	—	—
Second quarter dividends per share (yen)	50.00	—	50.00
Third quarter dividends per share (yen)	—	—	—
End-of-period dividends per share (yen)	—	50.00	50.00
Annual dividends per share (yen)	—	100.00	100.00

Note : Modifications in the dividend projection from the latest announcement : None

3. Consolidated Forecasts of results for the year ending March 31, 2015

(Percentage figures represent changes from same period of previous year.)

	Full year	% change
Net sales (millions of yen)	156,000	+4.9%
Operating income (millions of yen)	30,000	+9.4%
Ordinary income (millions of yen)	30,000	+7.4%
Net income (millions of yen)	19,500	+14.0%
Net income per share (yen)	236.26	

Note : Modifications in forecasts of consolidated results from the latest announcement : None

***Notes**

(1) Significant change in subsidiaries during the term (change in designated subsidiaries resulting in adjustment to the scope of consolidation) : No

Note : Seven companies, Santen Switzerland SA, Santen Italy S.r.l., Santen UK Limited, Santen Pharmaceutical Spain, S.L., SANTEN (THAILAND) CO., LTD., SANTEN PHARMA MALAYSIA SDN. BHD., and SANTEN PHILIPPINES INC. have newly become our consolidated subsidiaries.

(2) Application of special accounting method in the preparation of quarterly consolidated financial statements : No

(3) Changes in accounting policies, accounting estimates and restatements

[i] Changes in the accounting policies resulting from amendments to accounting standards : No

[ii] Changes other than [i] above : No

[iii] Changes in the accounting estimates : No

[iv] Restatements : No

(4) Number of shares outstanding (common stock)

[i] Number of shares outstanding at the end of period (including treasury stock)

December 31, 2014 : 82,619,403

March 31, 2014 : 82,582,903

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

December 31, 2014 : 3,537

March 31, 2014 : 2,324

[iii] Average number of outstanding shares (during the nine months ended December 31)

Third quarter ended December 31, 2014 : 82,601,102

Third quarter ended December 31, 2013 : 82,526,637

(Information regarding the application of accounting standards)

We plan to voluntarily adopt International Financial Reporting Standards (IFRS) from the fiscal year ending March 31, 2015 as announced on February 4, 2014, but the Consolidated Forecasts of results for the year ending March 31, 2015 above was prepared under Japanese Generally Accepted Accounting Principles (J-GAAP).

(Information regarding the implementation of quarterly review procedures)

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

(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.

Quarterly consolidated balance sheets

(Millions of yen)

	March 31, 2014	December 31, 2014
Assets		
Current assets		
Cash and deposits	63,509	58,303
Notes and accounts receivable-trade	52,086	56,577
Short-term investment securities	13,111	1,201
Merchandise and finished goods	16,223	14,122
Work in process	390	192
Raw materials and supplies	3,417	4,024
Deferred tax assets	2,346	1,559
Other	4,925	3,460
Allowance for doubtful receivables	(3)	(5)
Total current assets	156,006	139,436
Non-current assets		
Tangible assets		
Buildings and structures	45,033	45,886
Accumulated depreciation and impairment loss	(30,886)	(31,999)
Buildings and structures, net	14,146	13,886
Machinery, equipment and vehicles	13,453	14,297
Accumulated depreciation and impairment loss	(11,242)	(11,848)
Machinery, equipment and vehicles, net	2,210	2,448
Land	8,266	8,300
Lease assets	285	230
Accumulated depreciation and impairment loss	(129)	(62)
Lease assets, net	155	168
Construction in progress	816	1,656
Other	12,804	13,360
Accumulated depreciation and impairment loss	(10,772)	(11,243)
Other, net	2,032	2,116
Total tangible assets	27,628	28,578
Intangible assets		
Goodwill	6,297	5,846
In-process research and development	8,357	8,645
Manufacturing and marketing approval	—	59,561
Software	1,826	1,705
Other	102	230
Total intangible assets	16,585	75,989
Investments and other assets		
Investment securities	21,739	25,749
Deferred tax assets	5,488	4,424
Other	3,657	3,841
Total investments and other assets	30,885	34,015
Total non-current assets	75,099	138,583
Total assets	231,105	278,020

(Millions of yen)

	March 31, 2014	December 31, 2014
<u>Liabilities</u>		
Current liabilities		
Notes and accounts payable -trade	14,270	11,052
Current portion of long-term loans payable	—	11,767
Other payables	9,695	10,243
Income taxes payable	8,169	2,521
Provision for bonuses	3,573	2,296
Provision for sales returns	135	175
Other	3,249	5,171
Total current liabilities	39,093	43,228
Non-current liabilities		
Long-term loans payable	42	28,254
Lease obligations	59	68
Deferred tax liabilities	2,796	2,892
Net defined benefit liability	5,400	5,764
Provision for business structure improvement	802	863
Asset retirement obligations	221	223
Other	1,479	1,210
Total non-current liabilities	10,802	39,276
Total liabilities	49,896	82,504
<u>Net assets</u>		
Shareholders' equity		
Common stock	7,264	7,327
Capital surplus	7,958	8,021
Retained earnings	160,115	168,084
Treasury stock, at cost	(9)	(16)
Total shareholders' equity	175,328	183,416
Accumulated other comprehensive income		
Unrealized gains on securities, net of taxes	4,035	6,558
Foreign currency translation adjustments	2,574	5,988
Remeasurements of defined benefit plans	(1,128)	(1,015)
Total accumulated other comprehensive income(loss)	5,481	11,531
Stock subscription rights	399	567
Total net assets	181,209	195,515
Total liabilities and net assets	231,105	278,020

Quarterly consolidated statements of income and comprehensive income

(Millions of yen)

	Nine months ended December 31, 2013	Nine months ended December 31, 2014
Net sales	108,946	116,842
Cost of sales	42,751	41,470
Gross profit	66,374	75,371
Selling, general and administrative expenses	42,740	51,034
Operating income	23,633	24,337
Non-operating income		
Interest income	52	54
Dividend income	508	538
Other	302	330
Total non-operating income	863	924
Non-operating expenses		
Interest expense	5	62
Foreign exchange losses	93	217
Borrowing fee	—	99
Depreciation	85	48
Other	14	21
Total non-operating expenses	200	450
Ordinary income	24,297	24,811
Extraordinary income		
Gain on disposal of non-current assets	—	59
Gain on sales of investment securities	473	—
Total extraordinary income	473	59
Extraordinary loss		
Loss on disposal of non-current assets	17	—
Impairment loss	—	33
Loss on valuation of right of using facilities	1	—
Business structure improvement expenses	880	—
Total extraordinary loss	899	33
Income before income taxes	23,871	24,837
Income taxes - current	8,328	8,050
Income taxes - deferred	167	597
Total income taxes	8,495	8,647
Income before minority interests	15,376	16,190
Net income	15,376	16,190
Income before minority interests	15,376	16,190
Other comprehensive income		
Unrealized gains on securities, net of taxes	2,540	2,560
Foreign currency translation adjustments	4,590	3,414
Remeasurements of defined benefit plans	148	113
Other comprehensive income	7,279	6,088
Total comprehensive income	22,656	22,279
Total comprehensive income attributable to :		
Owners of the parent	22,656	22,279
Minority interests	—	—

Quarterly consolidated statements of cash flows

(Millions of yen)

	Nine months ended December 31, 2013	Nine months ended December 31, 2014
<u>Cash flows from operating activities:</u>		
Income before income taxes	23,871	24,837
Depreciation and amortization	2,060	4,800
Amortization of goodwill	584	649
Loss (gain) on sales of investment securities	(473)	—
Impairment loss	—	33
Business structure improvement expenses	880	—
Increase (decrease) in net defined benefit liability	131	524
Interest and dividend income	(561)	(593)
Interest expense	5	62
Decrease (increase) in notes and accounts receivable-trade	(8,330)	(4,058)
Decrease (increase) in inventories	3,283	2,113
Increase (decrease) in notes and accounts payable-trade	1,572	(3,259)
Other	(578)	1,538
Subtotal	22,446	26,647
Interest and dividend income received	568	604
Interest expense paid	(2)	(47)
Income taxes paid	(6,973)	(13,774)
Net cash provided by (used in) operating activities	16,038	13,430
<u>Cash flows from investing activities:</u>		
Increase in fixed deposits	(67)	(82)
Proceeds from withdrawal of fixed deposits	67	180
Purchase of short-term investment securities	(604)	—
Proceeds from sales and redemption of securities	1,906	2,906
Purchase of non-current assets	(3,548)	(64,127)
Proceeds from sales of non-current assets	2	69
Purchase of investment securities	(4,218)	(111)
Proceeds from sales of investment securities	512	40
Other	3	0
Net cash provided by (used in) investing activities	(5,946)	(61,124)
<u>Cash flows from financing activities:</u>		
Increase in short-term loans payable	—	35,000
Decrease in short-term loans payable	—	(35,000)
Proceeds from long-term loans payable	—	40,000
Dividends paid	(8,146)	(8,181)
Other	220	78
Net cash Provided by (used in) financing activities	(7,926)	31,896
Effect of exchange rate changes on cash and cash equivalents	1,566	1,683
Net increase (decrease) in cash and cash equivalents	3,732	(14,114)
Cash and cash equivalents at the beginning of period	59,797	72,396
Cash and cash equivalents at the end of period	63,529	58,281

Segment information

1. Nine months ended December 31, 2013

(Millions of yen)

	<Reporting segment> Pharmaceuticals	Other (Note)	Adjustments	Consolidated total
Net sales:				
External customers	106,821	2,124	—	108,946
Intersegment	—	93	(93)	—
Total	106,821	2,218	(93)	108,946
Segment income(loss)	23,996	(363)	—	23,633

Note: "Other" segment mainly includes medical equipment.

2. Nine months ended December 31, 2014

(Millions of yen)

	<Reporting segment> Pharmaceuticals	Other (Note)	Adjustments	Consolidated total
Net sales:				
External customers	114,928	1,913	—	116,842
Intersegment	—	471	(471)	—
Total	114,928	2,384	(471)	116,842
Segment income(loss)	24,424	(87)	—	24,337

Note: "Other" segment mainly includes medical equipment.

During the term, the assets of "Pharmaceuticals" segment increased so much as a result of purchasing assets of 59,561 million yen from Merck & Co., Inc.

<Reference>

■ Sales of major pharmaceuticals

(Millions of yen)

Brand name Generic name/formulation	Therapeutic category	Nine months ended December 31, 2013	Year ended March 31, 2014	Nine months ending December 31, 2014	Year ending March 31, 2015
		Actual	Actual	Actual	Forecasts
Cravit levofloxacin/ophthalmic solution	Bacterial conjunctivitis	9,396 8.2 %	12,845 18.3 %	9,419 0.2 %	12,178 (5.2) %
Tarivid ofloxacin/ophthalmic solution	Bacterial conjunctivitis	1,485 1.4 %	2,040 11.4 %	1,592 7.2 %	1,912 (6.3) %
Tapros tafluprost/ophthalmic solution	Glaucoma	6,974 14.1 %	9,509 20.8 %	6,904 (1.0) %	8,466 (11.0) %
Cosopt Dorzolamide hydrochloride/ timolol maleate ophthalmic solution	Glaucoma	9,226 35.7 %	11,846 31.5 %	8,641 (6.3) %	10,390 (12.3) %
Timoptol timolol maleate/ophthalmic solution	Glaucoma	947 (13.6) %	1,184 (13.3) %	934 (1.3) %	1,176 (0.7) %
Timoptol XE timolol maleate/ long-acting ophthalmic solution	Glaucoma	1,541 (6.8) %	1,931 (7.4) %	1,466 (4.9) %	2,002 3.7 %
Trusopt dorzolamide hydrochloride	Glaucoma	- - %	- - %	1,066 - %	1,925 - %
Detantol bunazosin hydrochloride	Glaucoma	1,188 (15.2) %	1,549 (10.7) %	960 (19.1) %	1,317 (15.0) %
Rescula isopropyl unoprostone	Glaucoma	1,687 (5.3) %	2,146 (4.3) %	1,517 (10.1) %	1,930 (10.1) %
Alesion epinastine HCl/ ophthalmic solution	Allergy	877 - %	2,103 - %	2,892 229.8 %	6,562 212.0 %
Livostin levocabastine hydrochloride/ ophthalmic solution	Allergy	1,371 (24.9) %	2,534 (37.2) %	1,261 (8.1) %	1,944 (23.3) %
Hyalain sodium hyaluronate/ophthalmic solution	Corneal disease	16,596 (0.9) %	21,823 3.1 %	15,199 (8.4) %	21,031 (3.6) %
Diquas diquafosol sodium/ophthalmic solution	Corneal disease	5,732 42.0 %	7,937 42.7 %	5,860 2.2 %	8,235 3.8 %
Flumetholon fluorometholone/ophthalmic solution	Inflammation	2,853 (5.2) %	3,973 (10.7) %	2,799 (1.9) %	3,964 (0.2) %
Kary Uni pirenoxine/ophthalmic solution	Early-stage senile cataract	3,008 1.2 %	4,059 7.8 %	3,051 1.4 %	4,161 2.5 %
Opegan Hi sodium hyaluronate/ adjuvant for ophthalmic operations	Adjuvant for ophthalmic operations	2,242 0.3 %	2,867 0.9 %	2,002 (10.7) %	2,654 (7.4) %
Eylea aflibercept/intravitreal injection	VEGF Trap-Eye	13,327 1,935.0 %	18,756 489.2 %	17,717 32.9 %	19,200 2.4 %
Rimatil bucillamine/tablet	Rheumatoid arthritis	2,482 (4.1) %	3,134 (3.7) %	2,059 (17.0) %	2,735 (12.7) %
Azulfidine EN sulfasalazine/enteric coated tablet	Rheumatoid arthritis	2,989 1.0 %	3,819 1.4 %	2,675 (10.5) %	3,619 (5.2) %
Metolate methotrexate/tablet	Rheumatoid arthritis	1,863 19.0 %	2,410 18.1 %	1,820 (2.3) %	2,363 (2.0) %
OTC pharmaceuticals		4,951 (4.7) %	6,455 (0.3) %	4,976 0.5 %	6,331 (1.9) %

lower: year on year percentage change

Percentages in parentheses indicate a decrease.

*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.

Reference information

Research & development

■ Pipeline of prescription pharmaceuticals (Clinical Stage)

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Tafluprost	DE-085	Glaucoma/ Ocular hypertension	Co-development with Asahi Glass	Asia						Mar-10
				China				Jan-11		

A prostaglandin $F_{2\alpha}$ derivative for the treatment of glaucoma and ocular hypertension. Since December, 2008, launched in Japan, Europe, and the U.S. In Asia, launched in Hong Kong, Korea, Indonesia, and Singapore, etc. NDA filed in China in January, 2011.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Diquafosol sodium	DE-089	Dry eye	Merck Sharp & Dohme Corp. (U.S.)	Asia						Oct-13
				China				Jan-12		

A dry eye treatment drug which stimulates secretion of mucin and aqueous components from the corneal epithelium. Its mechanism of action is different from other existing treatments. Launched in December, 2010 in Japan and in October, 2013 in Korea. NDA filed in China in January, 2012.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Lomerizine HCl	DE-090	Glaucoma	MSD K.K.	Japan						

A new type of glaucoma treatment which inhibits the progression of visual field defects. It is the only calcium antagonist being development as an oral glaucoma treatment. Compared to NMDA receptor antagonists, it has excellent safety profile with mild systemic adverse drug reactions.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Sirolimus	DE-109	Uveitis	Original	U.S.						
				Japan						
				Europe						

An intravitreal injection with immunosuppressive effect, anti-angiogenic effect, etc. Phase 3 study is ongoing in the U.S., Japan and Europe.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Tafluprost/ Timolol maleate	DE-111	Glaucoma/ Ocular hypertension	Co-development with Asahi Glass	Japan						Nov-14
				Europe						Jan-15
				Asia				Dec-14		

A fixed dose combination drug of a prostaglandin $F_{2\alpha}$ derivative and a beta-adrenergic receptor blocker. Launched in Japan in November, 2014. Approved appropriately in EU countries since October, 2014. Launched in Germany in January, 2015. NDA filed in Korea in December, 2014.

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

An EP2 receptor agonist with a new mechanism of action. Started Phase 2b in the U.S., in June, 2014.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Tafluprost	DE-118	Glaucoma/ Ocular hypertension	Co-development with Asahi Glass	Japan						Oct-13
				Asia				Mar-14		

A prostaglandin $F_{2\alpha}$ derivative for the treatment of glaucoma and ocular hypertension. Preservative-free, unit-dose type product. Launched in October, 2013 in Japan. NDA filed appropriately in Asian countries since March, 2014.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
(Undetermined)	DE-120	Wet Age-related macular degeneration	Original	U.S.	(Phase 1/2a)					

An intravitreal injection with dual inhibitor of VEGF and PDGF. Started on Phase 1/2a in the U.S., in January, 2014.

Reference information

Research & development

■ Santen S.A.S. pipeline of prescription pharmaceuticals (Clinical Stage)

Generic name	Dev. name	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Ciclosporin	Cyclokot	Severe dry eye	Original	Europe				Dec-13		
				U.S.						
An ophthalmic emulsion which improves symptoms and signs of severe dry eye by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue absorption.										
Ciclosporin	Vekacia	Vernal Keratoconjunctivitis	Original	Europe						
An ophthalmic emulsion which improves symptoms of vernal keratoconjunctivitis by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue absorption.										
Latanoprost	Catioprost	Glaucoma/ Ocular hypertension	Original	Europe						
An ophthalmic emulsion of a prostaglandin F _{2α} derivative, for the treatment of glaucoma and ocular hypertension.										
Dexamethasone Palmitate	Cortiject	Diabetic macular edema	Original	U.S.	(Phase 1/2)					
An intravitreal injection with anti-inflammatory effect.										

*Catioprost and Cortiject are under project evaluation.

■ Changes from 2Q FY14 (November 5, 2014)

Dev. Code / name	Changes
DE-111	Launched in November, 2014 (Japan) Approved in October, 2014 (EU) Launched in Germany in January, 2015 NDA filed in December, 2014 (Korea)

<Reference>

■ Capital expenditures

(Millions of yen)

	Nine months ended December 31, 2013 Actual	Year ended March 31, 2014 Actual	Nine months ended December 31, 2014 Actual	Year ending March 31, 2015 Forecasts
Capital expenditures	2,083	3,155	2,558	4,500

■ Depreciation and amortization

(Millions of yen)

	Nine months ended December 31, 2013 Actual	Year ended March 31, 2014 Actual	Nine months ended December 31, 2014 Actual	Year ending March 31, 2015 Forecasts
Consolidated total	1,830	2,612	4,579	6,700
Manufacturing cost	925	1,330	1,060	1,290
Selling, general and administrative expenses	446	648	3,020	4,620
R&D expenses	458	634	498	790

Notes: 1. Depreciation and amortization of above, are excluded amortization of long-term prepaid expenses and goodwill.
2. Amortization expenses from the intangible assets purchased from Merck & Co., Inc., are expected to be recorded as selling, general and administrative expenses. The total amount of amortization from the intangible assets from Merck & Co., Inc., is recorded 2,444 million yen for nine months ended December 31, 2014, and would be estimated 3,700 million yen for year ending March 31, 2015 Forecasts.

■ R&D expenses

(Millions of yen)

	Nine months ended December 31, 2013 Actual	Year ended March 31, 2014 Actual	Nine months ended December 31, 2014 Actual	Year ending March 31, 2015 Forecasts
R&D expenses	12,498	19,040	13,122	19,300
Net sales ratio	11.5%	12.8%	11.2%	12.4%

*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.