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SANTEN PHARMACEUTICAL CO., LTD.

Code: 4536

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

First Quarter Financial Results for the Fiscal Year Ending March 31, 2014 [Japan GAAP] (Consolidated)

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(Figures are rounded down to the nearest million yen)

1. Consolidated Performance for the three months ended June 30, 2013

(1) Operating results

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

	Three months ended June 30, 2013	Three months ended June 30, 2012	% change
Net sales (millions of yen)	34,314	27,958	22.7%
Operating income (millions of yen)	7,814	6,122	27.6%
Ordinary income (millions of yen)	8,218	6,546	25.5%
Net income (millions of yen)	5,562	4,277	30.0%
Net income per share (yen)	67.41	49.07	
Diluted net income per share (yen)	67.22	49.03	

Note: Comprehensive income:

First quarter ended June 30, 2013: ¥ 8,854 million(112.9%)

First quarter ended June 30, 2012: ¥ 4,158 million((30.9%))

(2) Financial condition

	June 30, 2013	March 31, 2013
Total assets (millions of yen)	203,556	199,640
Net assets (millions of yen)	168,500	165,132
Equity ratio	82.6%	82.6%
Net assets per share (yen)	2,038.46	1,998.44

Reference: Equity (Consolidated):

First quarter ended June 30, 2013: ¥ 168,198 million

Fiscal year ended March 31, 2013: ¥ 164,808 million

2. Dividends

	Year to March 2014	(Forecasts) Year to March 2014	Year to March 2013
First quarter dividends per share (yen)	0.00	—	0.00
Second quarter dividends per share (yen)	—	50.00	50.00
Third quarter dividends per share (yen)	—	0.00	0.00
End-of-period dividends per share (yen)	—	50.00	50.00
Annual dividends per share (yen)	—	100.00	100.00

3. Consolidated Forecasts of results for the year ending March 31, 2014

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

	First half year	Full year	(Full year) % change
Net sales (millions of yen)	66,500	134,500	13.0%
Operating income (millions of yen)	13,200	26,300	6.6%
Ordinary income (millions of yen)	13,500	26,800	4.7%
Net income (millions of yen)	9,200	18,200	10.2%
Net income per share (yen)	109.05	215.72	

***Notes**

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

(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: Yes

-Change in depreciation method for property, plant and equipment

The Company and its domestic subsidiary have changed depreciation method for property, plant and equipment from the declining-balance method (however, straight-line method was applied to buildings (other than leasehold improvements) acquired on or after April 1, 1998) to the straight-line method, from the first quarter of the current fiscal year.

As a result of this change, the major effects on the company's consolidated financial statements for the three months ended June 30, 2013 are as follows:

- Depreciation and amortization decreased by ¥149 million;
- Operating income increased by ¥85 million; and
- Ordinary income and income before income taxes increased by ¥88 million each.

-Application of Accounting standards and relevant regulations

- The "Accounting Standard for Retirement Benefits"(ASBJ Statement No.26, May 17, 2012)
- The "Guidance on Accounting Standard for Retirement Benefits"(ASBJ Guidance No.25, May 17, 2012)

The Company and its subsidiaries applied the accounting standard and relevant regulations from the beginning of this fiscal year.

As a result of this application, accumulated other comprehensive income decreased by ¥1,713 million and retained earnings increased by ¥227 million at the beginning of this fiscal year.

There are no material effects on the company's operating results for the three months ended June 30, 2013.

[iii] Changes in the accounting estimates: Yes

[iv] Restatements: No

(4) Number of shares outstanding (common stock)

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

June 30, 2013 : 82,513,703

March 31, 2013 : 82,469,103

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

June 30, 2013 : 1,085

March 31, 2013 : 900

[iii] Average number of outstanding shares (during the three months ended June 30)

First quarter ended June 30, 2013 : 82,510,735

First quarter ended June 30, 2012 : 87,154,172

(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, 2013	June 30, 2013
Assets		
Current assets		
Cash and deposits	50,884	45,361
Notes and accounts receivable-trade	43,840	47,420
Short-term investment securities	11,007	11,510
Merchandise and finished goods	16,703	16,256
Work in process	624	493
Raw materials and supplies	3,620	3,633
Deffered tax assets	1,880	1,207
Other	4,022	5,053
Allowance for doubtful receivables	(1)	(2)
Total current assets	132,582	130,934
Non-current assets		
Property, plant and equipment		
Buildings and structures	42,807	44,308
Accumulated depreciation and impairment loss	(29,379)	(29,840)
Buildings and structures, net	13,427	14,468
Machinery, equipment and vehicles	11,920	12,425
Accumulated depreciation and impairment loss	(10,336)	(10,606)
Machinery, equipment and vehicles, net	1,584	1,819
Land	8,240	8,253
Lease assets	251	270
Accumulated depreciation and impairment loss	(93)	(122)
Lease assets, net	158	148
Construction in progress	2,454	1,625
Other	11,833	12,268
Accumulated depreciation and impairment loss	(10,278)	(10,417)
Other, net	1,554	1,850
Total property, plant and equipment	27,420	28,167
Intangible assets		
Goodwill	5,936	6,065
In-process research and development	6,767	7,123
Software	1,150	1,160
Other	269	262
Total intangible assets	14,123	14,611
Investments and other assets		
Investment securities	18,173	22,306
Deferred tax assets	4,460	4,640
Other	2,879	2,895
Total investments and other assets	25,513	29,843
Total non-current assets	67,057	72,622
Total assets	199,640	203,556

(Millions of yen)

	March 31, 2013	June 30, 2013
<u>Liabilities</u>		
Current liabilities		
Notes and accounts payable -trade	9,266	9,627
Other payables	9,868	8,740
Income taxes payable	3,038	2,211
Provision for bonuses	3,085	1,543
Other	1,752	2,987
Total current liabilities	27,011	25,111
Non-current liabilities		
Deferred tax liabilities	2,269	2,387
Retirement and severance benefits for employee	3,664	—
Retirement and severance benefits for directors and auditors	248	—
Net defined benefit liability	—	6,078
Asset retirement obligations	160	221
Other	1,153	1,257
Total non-current liabilities	7,496	9,945
Total liabilities	34,507	35,056
<u>Net assets</u>		
Shareholders' equity		
Common stock	7,080	7,154
Capital surplus	7,775	7,848
Retained earnings	151,001	152,668
Treasury stock, at cost	(2)	(3)
Total shareholders' equity	165,855	167,667
Accumulated other comprehensive income		
Unrealized losses on securities, net of taxes	1,920	3,299
Foreign currency translation adjustments	(2,967)	(1,103)
Remeasurements of defined benefit plans	—	(1,664)
Total accumulated other comprehensive income(loss)	(1,047)	531
Stock subscription rights	324	301
Total net assets	165,132	168,500
Total liabilities and net assets	199,640	203,556

Quarterly consolidated statements of income and comprehensive income

	(Millions of yen)	
	Three months ended June 30, 2012	Three months ended June 30, 2013
Net sales	27,958	34,314
Cost of sales	9,448	13,501
Gross profit	18,509	20,812
Selling, general and administrative expenses	12,387	12,998
Operating income	6,122	7,814
Non-operating income		
Interest income	15	15
Dividend income	221	237
Dividends income of life insurance	157	147
Exchange gains	31	—
Other	40	52
Total non-operating income	466	454
Non-operating expenses		
Interest expenses	1	1
Exchange losses	—	9
Depreciation and amortization	—	35
Other	41	5
Total non-operating expenses	42	51
Ordinary income	6,546	8,218
Extraordinary income		
Gain on sales of fixed assets	16	—
Total extraordinary income	16	—
Extraordinary loss		
Loss on sales of non-current assets	—	1
Total extraordinary losses	—	1
Income before income taxes	6,563	8,216
Income taxes - current	1,451	2,036
Income taxes - deferred	834	617
Total income taxes	2,286	2,654
Income before minority interests	4,277	5,562
Net income	4,277	5,562
Income before minority interests	4,277	5,562
Other comprehensive income		
Unrealized gains(losses) on securities, net of taxes	116	1,379
Foreign currency translation adjustments	(235)	1,863
Remeasurements of defined benefit plans	—	49
Other comprehensive income	(118)	3,292
Total comprehensive income	4,158	8,854
Total comprehensive income attributable to :		
Owners of the parent	4,158	8,854
Minority interests	—	—

Quarterly consolidated statements of cash flows

(Millions of yen)

	Three months ended June 30, 2012	Three months ended June 30, 2013
<u>Cash flows from operating activities:</u>		
Income before income taxes	6,563	8,216
Depreciation and amortization	607	640
Amortization of goodwill	161	184
Increase (decrease) in retirement and severance benefits	52	—
Increase (decrease) in net defined benefit liability	—	168
Interest and dividend income	(236)	(253)
Interest expenses	1	1
Decrease (increase) in notes and accounts receivable-trade	(2,938)	(3,303)
Decrease (increase) in inventories	988	931
Increase (decrease) in notes and accounts payable-trade	(3,331)	299
Other, net	(2,984)	(2,585)
Subtotal	(1,116)	4,300
Interest and dividend income received	236	255
Interest expenses paid	(0)	(0)
Income taxes paid	(5,158)	(2,897)
Net cash provided by (used in) operating activities	(6,038)	1,657
<u>Cash flows from investing activities:</u>		
Increase in fixed deposits	(38)	(45)
Proceeds from withdrawal of fixed deposits	166	45
Purchase of short-term investment securities	(301)	—
Proceeds from sales of short-term investment securities	707	400
Capital expenditures	(705)	(1,308)
Proceeds from sales of fixed assets	30	0
Purchase of investment securities	(1,211)	(2,903)
Other	0	0
Net cash provided by (used in) investing activities	(1,351)	(3,811)
<u>Cash flows from financing activities:</u>		
Dividends paid	(4,247)	(4,018)
Other, net	10	120
Net cash Provided by (used in) financing activities	(4,237)	(3,897)
Effect of exchange rate changes on cash and cash equivalents	(453)	520
Net increase (decrease) in cash and cash equivalents	(12,080)	(5,530)
Cash and cash equivalents at beginning of period	75,035	59,797
Cash and cash equivalents at end of period	62,955	54,266

Segment information

1. Three months ended June 30, 2012

(Millions of yen)

	<Reporting segment> Pharmaceuticals	Other (Note)	Adjustments	Consolidated total
Net sales:				
External customers	27,448	509	—	27,958
Intersegment	—	30	(30)	—
Total	27,448	540	(30)	27,958
Segment income(loss)	6,335	(212)	—	6,122

Note: "Other" segment mainly includes medical equipment.

2.(1) Three months ended June 30, 2013

(Millions of yen)

	<Reporting segment> Pharmaceuticals	Other (Note)	Adjustments	Consolidated total
Net sales:				
External customers	33,627	686	—	34,314
Intersegment	—	32	(32)	—
Total	33,627	719	(32)	34,314
Segment income(loss)	7,911	(96)	—	7,814

Note: "Other" segment mainly includes medical equipment.

(2) Change in depreciation method for property, plant and equipment

The Company and its domestic subsidiary have changed depreciation method for property, plant and equipment from the declining-balance method (however, straight-line method for buildings (other than leasehold improvements) acquired on or after April 1, 1998) to the straight-line method from the first quarter of the current fiscal year.

As a result of this change, segment income of "Pharmaceuticals" segment increased by ¥85 million for the three months ended June 30, 2013. There are no material effects on "Other" segment.

<Reference>

■ Sales of major pharmaceuticals

(Millions of yen)

Brand name Generic name/formulation	Therapeutic category	Three months ended June 30, 2012	Six months ended September 30, 2012	Year ended March 31, 2013	Three months ended June 30, 2013	Six months ending September 30, 2013	Year ending March 31, 2014
		Actual	Actual	Actual	Actual	Forecasts	Forecasts
Cravit levofloxacin/ophthalmic solution	Bacterial conjunctivitis	2,697 (16.4) %	5,769 (14.8) %	10,857 (12.2) %	2,942 9.1 %	6,197 7.4 %	11,928 9.9 %
Tarivid ofloxacin/ophthalmic solution	Bacterial conjunctivitis	455 (1.4) %	965 (6.9) %	1,830 (5.3) %	494 8.7 %	989 2.5 %	1,950 6.5 %
Tapros tafluprost/ophthalmic solution	Glaucoma	1,951 9.6 %	3,933 8.0 %	7,872 7.1 %	2,172 11.3 %	4,523 15.0 %	9,266 17.7 %
Cosopt Dorzolamide hydrochloride/ timolol maleate Ophthalmic Solution	Glaucoma	2,091 55.2 %	4,252 50.1 %	9,006 43.6 %	2,846 36.1 %	4,917 15.6 %	9,470 5.2 %
Timoptol timolol maleate/ophthalmic solution	Glaucoma	384 (17.7) %	730 (19.4) %	1,366 (19.7) %	325 (15.5) %	650 (11.0) %	1,159 (15.2) %
Timoptol XE timolol maleate/ long-acting ophthalmic solution	Glaucoma	573 (12.7) %	1,099 (13.4) %	2,085 (13.3) %	517 (9.8) %	1,041 (5.3) %	1,923 (7.8) %
Detantol bunazosin hydrochloride	Glaucoma	500 (1.8) %	948 (5.7) %	1,734 (11.9) %	401 (19.8) %	720 (24.1) %	1,304 (24.8) %
Rescula isopropyl unoprostone	Glaucoma	594 (8.2) %	1,164 (9.3) %	2,243 (9.3) %	550 (7.4) %	1,107 (4.9) %	2,187 (2.5) %
Livostin levocabastine hydrochloride/ ophthalmic solution	Allergy	569 (2.9) %	1,176 (1.7) %	4,036 20.6 %	297 (47.8) %	1,774 50.8 %	3,250 (19.5) %
Hyalein sodium hyaluronate/ophthalmic solution	Corneal disease	5,216 (5.6) %	10,884 (3.9) %	21,159 (4.8) %	5,497 5.4 %	10,429 (4.2) %	20,628 (2.5) %
Diquas diquafosol sodium/ophthalmic solution	Corneal disease	1,084 108.2 %	2,244 100.1 %	5,563 95.5 %	1,754 61.8 %	3,718 65.6 %	7,788 40.0 %
Flumetholon fluorometholone/ophthalmic solution	Inflammation	1,003 8.9 %	2,002 0.6 %	4,447 9.2 %	807 (19.5) %	2,094 4.6 %	4,089 (8.1) %
Kary Uni pirenoxine/ophthalmic solution	Early-stage senile cataract	953 1.9 %	1,947 1.4 %	3,765 2.1 %	943 (1.0) %	2,072 6.4 %	4,074 8.2 %
Opegan Hi sodium hyaluronate/ adjuvant for ophthalmic operations	Adjuvant for ophthalmic operations	739 (3.1) %	1,439 (6.3) %	2,842 (5.8) %	714 (3.4) %	1,535 6.7 %	3,001 5.6 %
Eylea aflibercept/intravitreal injection	VEGF Trap-Eye	— —	— —	3,183 —	3,893 —	4,538 —	9,852 209.5 %
Rimatil bucillamine/tablet	Rheumatoid arthritis	891 (11.7) %	1,697 (13.0) %	3,253 (11.4) %	839 (5.8) %	1,625 (4.3) %	3,057 (6.0) %
Azulfidine EN salazosulfapyridine/enteric coated tablet	Rheumatoid arthritis	1,004 (5.0) %	1,934 (6.5) %	3,767 (6.5) %	994 (0.9) %	1,882 (2.7) %	3,568 (5.3) %
Metolate methotrexate/tablet	Rheumatoid arthritis	501 25.8 %	1,006 23.3 %	2,040 19.6 %	595 18.8 %	1,258 25.1 %	2,590 27.0 %
OTC pharmaceuticals		1,457 26.8 %	3,180 30.0 %	6,474 40.8 %	1,512 3.8 %	3,367 5.9 %	6,727 3.9 %

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_{2α} derivative for the treatment of glaucoma and ocular hypertension. Launched in Japan in December, 2008. In Europe, launched in Germany, Denmark, etc. In the countries including the U.S., development rights were granted to Merck & Co., Inc. (U.S.) in April, 2009. In Asia, launched in Hong Kong, Korea, Indonesia, and Singapore. NDA filed in China.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Diquafosol sodium	DE-089	Dry eye	Inspire (Merck)	Asia						Dec-11
				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. Approved in Korea, and NDA filed in China.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Lomerizine HCl	DE-090	Glaucoma	MSD	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
Betamethasone	DE-102	Macular edema secondary to diabetes and BRVO*	Co-development with Oakwood	Japan	(Phase 2/3)					

A microsphere product with a new drug delivery concept. Stable and sustained efficacy is expected with a local injection. Collaborating with Oakwood Laboratories (U.S.) for manufacturing technology development on commercial scale. *BRVO: Branch retinal vein occlusion.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
(Undetermined)	DE-105	Persistent corneal epithelial defects	Original	U.S.						
				Japan						

Expected to accelerate corneal epithelial extension and demonstrate high safety profile in treatment-resistant, persistent corneal epithelial defects.

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., Europe and Japan.

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						Oct-12
				Europe						June-13

A combination drug of a prostaglandin F_{2α} derivative and a beta-adrenergic receptor blocker. NDA filed in June, 2013 in Europe.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Epinastine HCl	DE-114	Allergic conjunctivitis	Nippon Boehringer Ingelheim	Japan						Nov-12

An H1 receptor antagonist with membrane-stabilizing function, as treatment for allergic conjunctivitis. NDA filed in November, 2012.

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
(Undetermined)	DE-117	Glaucoma/ Ocular hypertension	Co-development with Ube Industries	U.S.	(Phase 1/2a)					
A prostaglandin EP2 receptor agonist with a new mechanism of action. Phase 1/2a was started in the U.S.										

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					Jan-13	
A prostaglandin F _{2α} derivative for the treatment of glaucoma and ocular hypertension. Preservative-free, unit-dose type product. Approved in January, 2013 in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
(Undetermined)	DE-098 (Anti-APO-1 antibody)	Rheumatoid arthritis	Janssen Biotech	Japan						
A joint injection inducing apoptosis in diseased joints of rheumatoid arthritis patients. Next development plan is under evaluation based on Phase 2 study results.										

■ 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	Cyclokat	Severe dry eye	Original	Europe						
				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 the 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 12FY4Q (May 8, 2013)

Dev. code	Changes
DE-101	Development discontinued (Santen judged it cannot meet the expected achievement criteria)
DE-111	NDA filed (Europe)

<Reference>

■ Capital expenditures

(Millions of yen)

	Three months ended June 30, 2012	Six months ended September 30, 2012	Year ended March 31, 2013	Three months ended June 30, 2013	Six months ending September 30, 2013	Year ending March 31, 2014
	Actual	Actual	Actual	Actual	Forecasts	Forecasts
Capital expenditures	459	1,872	4,202	1,027	2,670	6,170

■ Depreciation and amortization

(Millions of yen)

	Three months ended June 30, 2012	Six months ended September 30, 2012	Year ended March 31, 2013	Three months ended June 30, 2013	Six months ending September 30, 2013	Year ending March 31, 2014
	Actual	Actual	Actual	Actual	Forecasts	Forecasts
Consolidated total	589	1,200	2,530	561	1,350	2,890
Manufacturing cost	272	580	1,211	273	660	1,370
Selling, general and administrative expenses	144	276	533	134	350	770
R&D expenses	172	344	785	153	340	750

■ R&D expenses

(Millions of yen)

	Three months ended June 30, 2012	Six months ended September 30, 2012	Year ended March 31, 2013	Three months ended June 30, 2013	Six months ending September 30, 2013	Year ending March 31, 2014
	Actual	Actual	Actual	Actual	Forecasts	Forecasts
R&D expenses	4,005	7,942	16,719	3,845	8,900	18,200
Net sales ratio	14.3%	14.0%	14.0%	11.2%	13.4%	13.5%

*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.