

First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2012

- Overview of consolidated results
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- Segment information for the First Quarter of the Fiscal Year Ending March 31, 2012
- Consolidated Financial Results for the First Quarter of the Fiscal Year Ending March 31, 2012

July 29, 2011

KYORIN Holdings, Inc.

These forecast performance figures are based on information currently available to the Company and may include uncertain factors or risk that affect our future performance. Accordingly, actual business results may materially differ from the forecasted figures due to various factors in the future.



Outline of First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2012



Units: Millions of yen	First quarter June 30, 2008	First quarter June 30, 2009	First quarter June 30, 2010	First quarter June 30, 2011	YoY change (%)	Sep/11 Interim term (forecast)	YoY change (%)	Year ending March 31, 2012 (forecast)	YoY change (%)
Net sales	20,756	23,289	24,655	24,809	0.6%	49,200	5.3%	106,500	2.3%
Operating income	995	3,156	2,216	4,100	85.0%	6,100	45.2%	16,600	1.0%
Ordinary income	1,228	3,417	2,421	4,300	77.6%	6,400	40.9%	17,200	0.5%
Net income	540	1,976	1,799	2,697	49.9%	4,000	35.2%	10,900	△0.3%

First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2012

【 Net sales】

Of ethical drugs in Japan, sales of Kipres and Uritos were strong, but overall ethical drug sales in Japan declined slightly year on year, reflecting an increase in distribution inventory at the end of the fiscal year ended March in association with the Great East Japan Earthquake. Sales of overseas ethical drugs rose from a year ago, attributable to strong exports of mainstay products. As a result, consolidated net sales increased 0.6% year on year, to ¥24,809 million.

【Income】

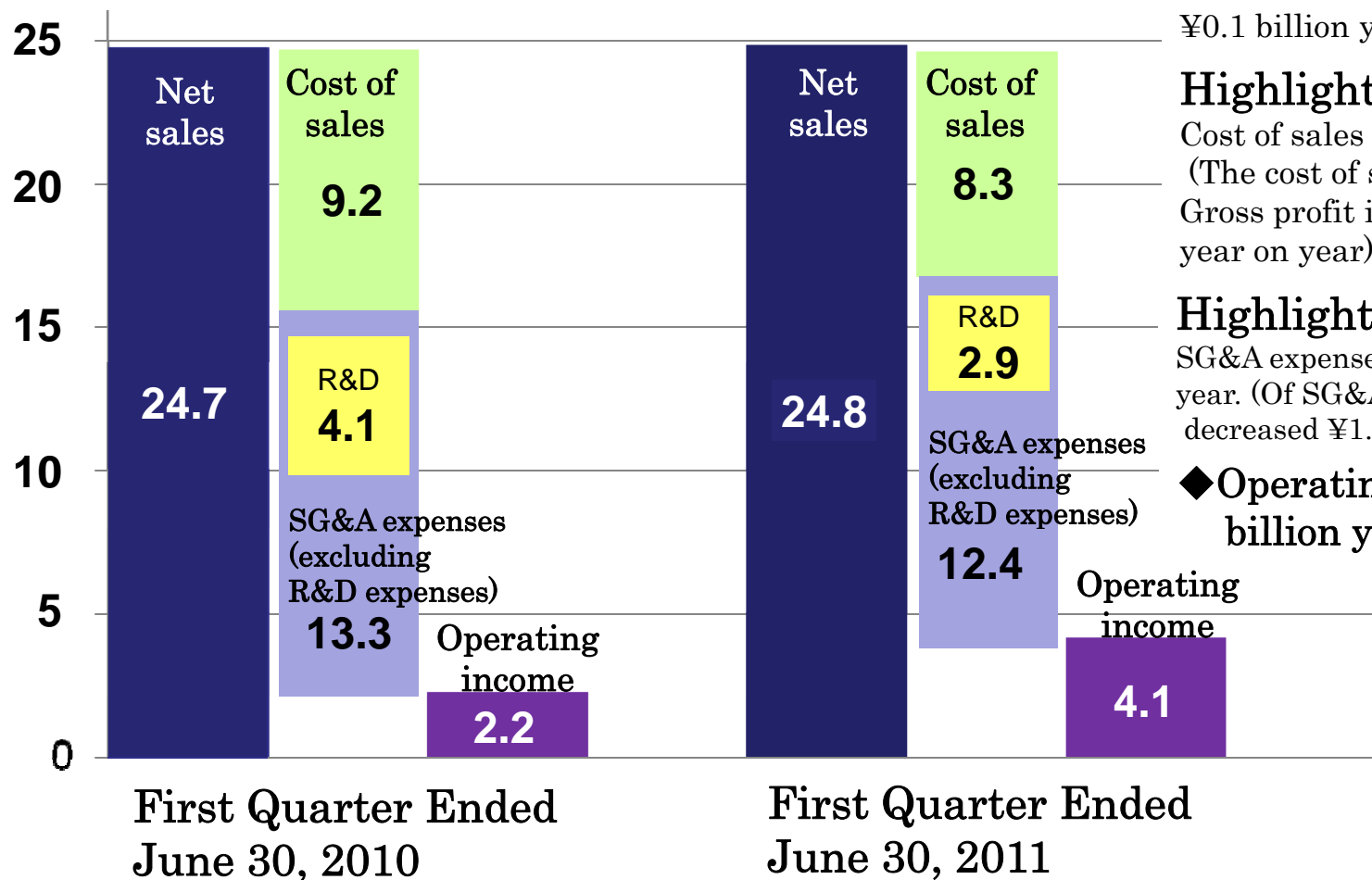
Gross profit rose due to a decline in the cost of sales ratio. Meanwhile, SG&A expenses fell, given a decrease in R&D expenses. Consequently, operating income climbed 85.0% year on year, to ¥4,100 million, and net income rose 49.9%, to ¥2,697 million.

Consolidated Financial Results for the Fiscal Year Ending March 31, 2012(forecast)

The results forecasts for the first half and the full year announced on May 11, 2011 remain unchanged. (Progress compared with the forecast for the first half: net sales: 50.4%; operating income: 67.2%)

Highlights of Business Performance for the First Quarter Ended June 30, 2011

(Units: ¥ billion)



Highlight ①

Net sales remained flat (rose ¥0.1 billion year on year).

Highlight ②

Cost of sales declined ¥0.9 billion.
(The cost of sales ratio fell 3.8 points.)
Gross profit increased (up ¥1 billion year on year).

Highlight ③

SG&A expenses dropped ¥0.9 billion year on year. (Of SG&A expenses, R&D expenses decreased ¥1.2 billion.)

◆ **Operating income rose ¥1.9 billion year on year.**

Consolidated Financial Results for the First Quarter Ended June 30, 2011



(Units: ¥ billion)

	First Quarter June 30, 2010	First Quarter June 30, 2011	Change
Net sales (total)	24.7	24.8	+0.1
Ethical drugs business	24.0	24.2	+0.2
◆ Sales of new ethical drugs	20.8	21.1	+0.3
○ Japan	20.2	20.1	△0.1
○ Overseas	0.6	1.1	+0.5
◆ Generic drugs	2.1	2.1	△0.0
◆ Over-the-counter drugs	1.0	1.0	△0.0
Healthcare (Skin care) Business	0.7	0.6	△0.1

Operating income	2.2	4.1	+1.9
Ordinary Income	2.4	4.3	+1.9
Net income	1.8	2.7	+0.9

		Year on Year
■ Net sales	¥24.8billion	(+0.1)
◆ Ethical drugs business	¥24.2billion	(+0.2)
● Sales of new ethical drugs in Japan	¥20.1billion	(△0.1)
	11.3(1Q) (results) 12.3(1Q) (results)	
・ Kipres	7.4 ⇒ 8.3	(+0.9)
・ Mucodyne	1.3 ⇒ 1.6	(+0.3)
・ Pentasa	5.6 ⇒ 5.1	(△0.5)
・ Uritos	5.0 ⇒ 4.6	(△0.4)
● Sales of new ethical drugs in Overseas	¥1.1billion	(+0.5)
・ ガチフロキサシン	0.5 ⇒ 1.0	(+0.5)
◆ Healthcare (Skin care) Business	¥0.6billion	(△0.1)
● Sales declined at Dr. Program Co., Ltd.		(△0.1)
■ Operating income	¥4.1billion	(+1.9)
◆ Operating income margin rose 7.5 percentage points YoY to 16.5%.		
● Cost of sales ratio: 33.4%, down 3.8 percentage points YoY		(37.2%⇒33.4%)
	Increased sales of in-house products with lower cost of sales ratios (including overseas sales), a rise in the factory operation ratio, and a decrease in the cost of sales ratio at KYORIN Rimedio	
● R&D ratio: 11.8%, down 5.0 percentage points YoY		(16.8%⇒11.8%)
* ¥4.1 billion ⇒ ¥2.9 billion (down ¥1.2 billion)		
	(Expenses associated with the completion of the R&D of KRP-108 Ph2b were posted in the first quarter of the previous fiscal year)	
● SG&A ratio (excluding R&D expenses): 38.3%, up 1.3 percentage points YoY		(37.0%⇒38.3%)
* ¥9.1 billion ⇒ ¥9.5 billion (up ¥0.4 billion)		
■ Net income	¥2.7billion	(+0.9)

Actual and Forecast of Main Subsidiary Companies

(Units: ¥ billion)

KYORIN pharmaceutical	First quarter June 30, 2010 (results)	First quarter June 30, 2011 (results)	FY 2010 (results)	FY2011 (forecast)
Sales	21.5	22.5	92.5	95.1
Operating profit	2.0	3.9	15.6	15.7
Net profit	1.7	2.7	10.7	10.4

KYORIN Rimedio	First quarter June 30, 2010 (results)	First quarter June 30, 2011 (results)	FY 2010 (results)	FY2011 (forecast)
Sales	2.4	2.4	10.3	11.0
Operating profit	0.2	0.3	0.8	0.7
Net profit	0.2	0.2	0.6	0.7

Dr.Program	First quarter June 30, 2010 (results)	First quarter June 30, 2011 (results)	FY 2010 (results)	FY2011 (forecast)
Sales	0.7	0.6	2.8	3.0
Operating profit	△0.0	△0.0	0.1	0.1
Net profit	△0.0	△0.0	0.1	0.0

Main Product Sales Update

(Units: ¥ billion)

Product name		Interim term		Full term		First quarter (April 1 to June 30)				
		FY2010 (results)	FY2011 (forecast)	FY2010 (results)	FY2011 (forecast)	FY2010 (results)	FY2011 (results)	YoY change (%)	Progress to Interim term forecast(%)	Progress to Full term forecast(%)
Sales of new ethical drugs (Japan)	Kipres (LT receptor antagonist)	14.1	16.2	34.5	36.5	7.4	8.3	12.0%	51.1%	22.6%
	Mucodyne (Mucoregulant)	9.4	9.7	21.3	22.1	5.6	5.1	△8.7%	52.4%	22.9%
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	9.9	9.7	19.4	19.2	5.0	4.6	△8.3%	46.9%	23.7%
	Uritos (Kyorin) (Overactive bladder)	2.4	3.0	5.5	6.6	1.3	1.6	24.3%	52.4%	23.5%
	Ketas (For bronchial asthma and cerebrovasculas disorders)	2.0	1.8	4.0	3.8	1.0	0.9	△13.4%	48.8%	24.8%
Sales of new ethical drugs (over seas)	Gatifloxacin (Bulk · Royalty)	1.3	1.1	2.2	1.2	0.5	1.0	94.3%	92.0%	77.0%
Over-the-counter drugs	Milton (Disinfectant)	0.9	1.0	1.9	2.0	0.5	0.5	△0.9%	47.2%	23.0%

Sales of Gatifloxacin included bulk sales to licensees and running royalties in accordance with sales at licensees.

Main R&D Activities① (July 29 , 2011 Release)



Ph IIb Application submitted

*Changes from the previous announcement
(May 11, 2011)

Stage		Compound/ Code	Therapy area/Action	Origin	Features	Comments
Japan	Overseas					
Ph III (12/2009)		Pentasa (tablet)	Ulcerative colitis	Ferring Pharmaceuticals	New dosage regimen for ulcerative colitis in the remission phase (once a day)	
Ph III (11/2010)		Pentasa (suppository)	Ulcerative colitis	Ferring Pharmaceuticals	Consideration of a new dosage form for the active phase of ulcerative colitis (once a day)	*Development of a new dosage form
Ph III (8/2010)	(US) SkyePharma : Application submitted (3/2009) (Europe) Mundipharma : Application submitted (3/2010)	KRP-108 (Inhalant)	Anti- asthmatic	SkyePharma PLC	An ICS/LABA combination product, which offers better compliance and convenience to the patients	*License agreement with SkyePharma (4/2008) *Domestic Ph II completed (4/2010)
Ph II (2/2008)	Ph II (9/2007)	KRP-104	Anti- diabetes agent	In-house	A DPPIV inhibitor to reduce blood glucose through suppression of the degradation of insulin-releasing hormone. Diabetic therapy with fewer side effects is expected than existing treatments.	*Overseas Ph II b completed (3/2011) *Domestic Ph II b completed (3/2010)

* The Company has cancelled the AS-3201 (diabetic neuropathy) co-development agreement with Dainippon Sumitomo for strategic reasons and has deleted AS-3201 from the list of R&D activities.

Main R&D Activities② (July 29 , 2011 Release)



POC Project (Pre-clinical ~ Ph II)						
Stage		Compound/ Code	Therapy area/Action	Origin	Features	Comments
Japan	Overseas					
Ph I (12/2010)	Ph II (POC) (12/2010) (Novartis)	KRP-203	Transplantation, autoimmune diseases,and IBD	In-house	An immunosuppressant with a novel mechanism called an S1P-agonist. It may have a better safety profile than previous ones as well as an excellent effect under concomitant use with other types of immunomodulator.	License agreement with Novartis (2/2006) New license agreement IBD (11/2010)
	Ph I (8/2010)	KRP-110	Opioid-induced constipation and intractable pruritus	In-house	A highly selective μ -opioid receptor antagonist. It is expected to block constipation induced by opioid analgesics without interrupting the analgesic effect of opioids. It is orally effective in various itching models, indicating potential of a novel anti-itch drug for intractable pruritus.	
Ph II preparations	Ph III Merz	KRP-209	Tinnitus	Merz	KRP-209 (Neramexane) is expected to improve the patients' annoyance and difficulties in their life caused by tinnitus, mainly through its two pharmacological properties: 1) NMDA antagonistic activity and 2) Nicotinic acetylcholine antagonistic activity	License agreement with Merz (11/2009) Merz:Ph I clinical trial of Japanese patients in US completed (3/2010)
Preparing for clinical trials	(Europe) Almirall : Preparing for application (US) Forest Pharmaceuticals : Preparing for application	KRP-AB1102 (Inhaled drug)	Chronic Obstructive Pulmonary Disease (COPD)	Almirall	This bronchodilating agent has an acetylcholine receptor antagonist action that offers long-lasting improvement for breathing difficulty and shortness of breath associated with COPD. ①Fewer systemic side effects ②Twice-daily dosage offers a full-day improvement in symptoms and respiratory function ③Short time required for the maximum effect	License agreement with Almirall (2/2011)
Ph I preparations		KRP-AM1977X (Oral agent)	New quinolone synthetic antibacterial agent	In-house	①Superior ability to combat drug-resistant gram-positive bacteria (incl. MRSA) ②Outstanding ADME (oral absorption, tissue migration) ③High degree of safety expected since safety hurdles cleared prior to clinical trials	
Ph I preparations		KRP-AM1977Y (Injection)	New quinolone synthetic antibacterial agent	In-house		

Main R&D Activities③ (July 29, 2011 Release)



Licensing Development

Stage	Compound/Code	Licensee/Collaborative research	Therapy area/Action	Origin	Comments
Application submitted (3/2011)	Alphagan /AlphaganP	Senju Pharmaceuticals	Glaucoma	Allergan (US)	<ul style="list-style-type: none"> •Licensed from Allergan (Cross license of gatifloxacin ophthalmic solution) •License-out to Senju (5/2004)
Overseas Ph II (8/2005)	Ketas	MediciNova (US)	Cerebrovascular disorders	In-house	<ul style="list-style-type: none"> •KYORIN grants MediciNova an exclusive license in all countries worldwide except for Japan, China, South Korea and Taiwan to develop, manufacture and sell the compound and products for the multiple sclerosis indication (10/2004) Result of Ph II was reported in April 2008
Overseas Ph III (Anti-bronchial Asthma: 11/2006) Overseas Ph II/III (Interstitial cystitis: 5/2005)	KCA-757	MediciNova (US)	Bronchial asthma and interstitial cystitis	In-house	<ul style="list-style-type: none"> •KYORIN grants MediciNova an exclusive license in all countries worldwide except for Japan, China, South Korea and Taiwan to develop and sell the compound and products •Interstitial cystitis: Result of Ph II/III was reported in January 2007 and development ceased •Bronchial asthma: Clinical trial overseas was discontinued.
Overseas Ph II (POC) (12/2010)	KRP-203	Novartis (Switzerland)	Transplantation, autoimmune, and IBD*	In-house	<ul style="list-style-type: none"> •Kyorin grants the right to develop and commercialize KRP-203 worldwide for use as an immunosuppressant in organ transplants, and right to develop and commercialize KRP-203 worldwide except in Japan, Korea, China and Taiwan for the treatment of autoimmune diseases and other diseases (February 2006) •New license agreement IBD (November 2010)

Reference

Segment information for the First Quarter Ended June 30, 2011

Sales, profit or loss of each report segment

(Units: ¥ billion)

	Sales	Year on Year	Profit	Year on Year
Net sales (total)	24.8	+0.2	4.1	+1.9
Ethical drugs business	24.2	+0.2	4.1	+1.9
◆Sales of new ethical drugs	21.1	+0.4		
○Japan	20.1	△0.1		
○Overseas	1.1	+0.4		
◆Generic drugs	2.1	△0.1		
◆Over-the-counter drugs	1.0	△0.0		
Healthcare(Skincare) business	0.6	△0.1	△0.0	△0.0
Amount of adjustment	△0.0		0.1	△0.0

(Note) The Company is applying the Revised Accounting Standard for Disclosures about Segments of an Enterprise and Related Information and the Guidance on the Accounting Standard for Disclosures about Segments of an Enterprise and Related Information. As a result, the reported segments are the Ethical Drugs Business and the Consumer Healthcare Business.

Consolidated Financial Results for the First Quarter Ended June 30, 2011



(Units: ¥ million)

	Interim term		Full term		First quarter (April 1 to June 30)					
	FY2010 (results)	FY2011 (forecast)	FY2010 (results)	FY2011 (forecast)	FY2010 (results)	FY2011 (results)	Change	YoY change (%)	Progress to interim term forecast (%)	Progress to full term forecast (%)
Sales	46,707	49,200	104,069	106,500	24,655	24,808	153	0.6%	50.4%	23.3%
◆ Ethical drugs business	45,373	47,800	101,271	103,500	23,955	24,182	227	0.9%	50.6%	23.4%
Sales of new ethical drugs	39,208	41,200	88,020	88,900	20,794	21,148	354	1.7%	51.3%	23.8%
Japan	37,708	39,900	85,284	87,100	20,167	20,076	△91	△0.5%	50.3%	23.0%
Overseas	1,500	1,300	2,736	1,700	626	1,072	446	71.2%	82.5%	63.1%
Generic drugs	4,115	4,600	8,871	10,300	2,145	2,068	△77	△3.6%	45.0%	20.1%
Over-the- counter drugs	2,049	2,000	4,378	4,300	1,015	966	△49	△4.8%	48.3%	22.5%
◆ healthcare (Skincare) business	1,333	1,400	2,797	3,000	699	626	△73	△10.4%	44.7%	20.9%
Operating income	4,201	6,100	16,443	16,600	2,216	4,100	1,884	85.0%	67.2%	24.7%
Ordinary Income	4,542	6,400	17,110	17,200	2,421	4,300	1,879	△29.2%	67.2%	25.0%
Net income	2,959	4,000	10,927	10,900	1,799	2,697	898	49.9%	67.4%	24.7%