

First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2011

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- Consolidated Financial Results for the First Quarter of the Fiscal Year Ending March 31,2011
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July 30, 2010

KYORIN Holdings, Inc.



Outline of First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2011



Units: Millions of yen	First quarter June 30, 2007	First quarter June 30, 2008	First quarter June 30, 2009	First quarter June 30, 2010	YoY change (%)
Net sales	21,891	20,756	23,289	24,655	5.9%
Operating income	4,082	995	3,156	2,216	△29.8%
Ordinary income	4,321	1,228	3,417	2,421	△29.2%
Net income	2,600	540	1,976	1,799	△9.0%

Sep/10 Interim term (forecast)	YoY change (%)	Year ending March 31, 2011 (forecast)	YoY change (%)
46,500	1.7%	100,300	0.5%
2,500	△45.3%	12,700	△4.2%
2,900	△43.9%	13,400	△5.9%
1,700	△48.4%	8,500	△3.9%

First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2011

< Year on Year >

【Net sales】 Although prices of ethical drugs were revised, sales of new ethical drugs in Japan rose on a year-on-year basis. Sales of generic drugs also increased. As a result, consolidated net sales stood at ¥24.6 billion, up 5.9% year on year.

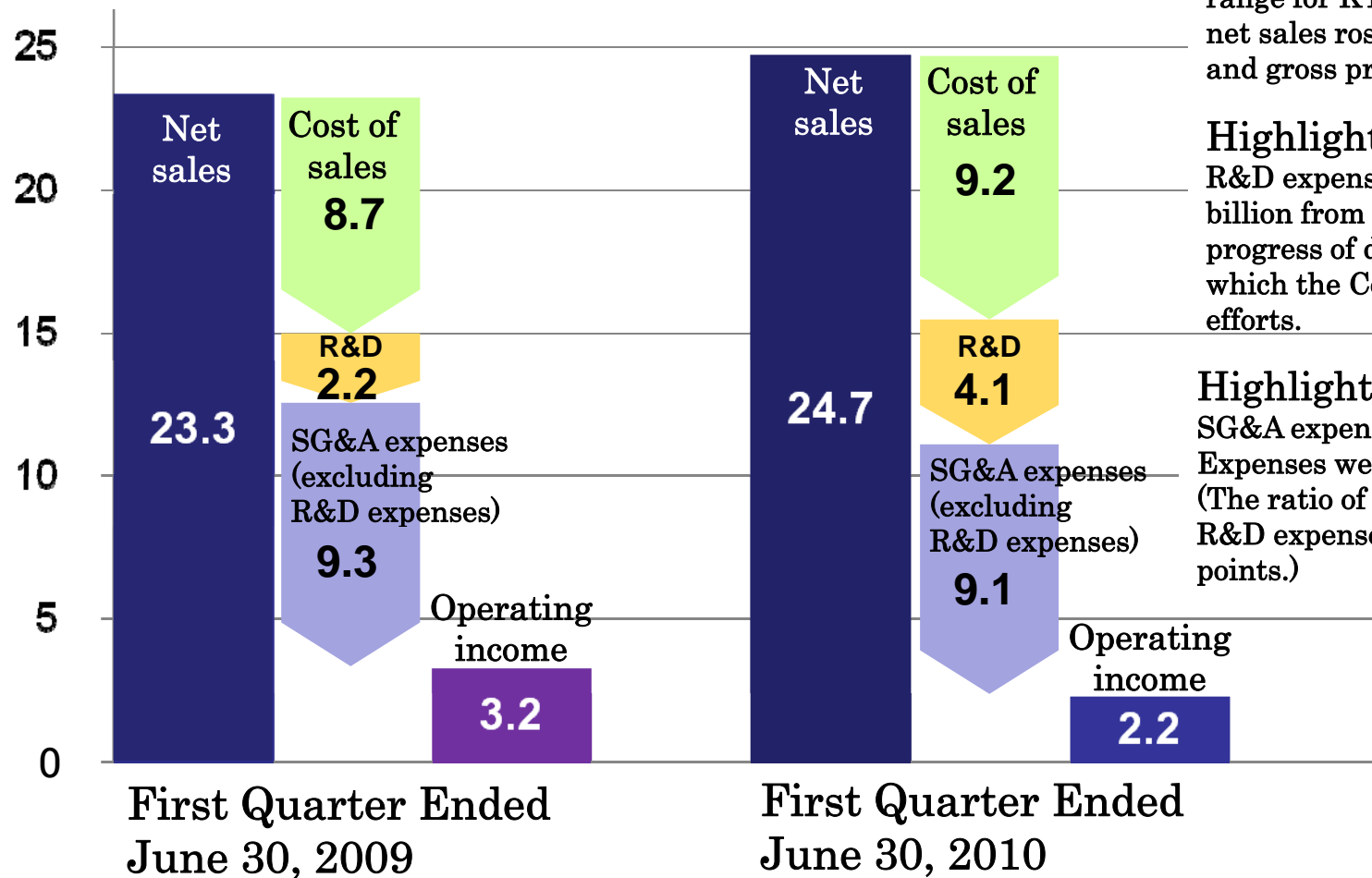
【Income】 With the increase in net sales, gross profit rose. However, R&D expenses also increased (up 89.3% year on year). Consequently, operating income was ¥2.2 billion (down 29.8% year on year), and net income was ¥1.8 billion (falling 9.0%).

Consolidated Financial Results for the Fiscal Year Ending March 31, 2011 (forecast)

The results forecasts for the first half and the full year announced on May 11, 2010 remain unchanged. (Progress compared with the forecast for the first half: net sales: 53.0%; operating income: 88.6%)

Highlights of Business Performance for the First Quarter Ended June 30, 2010

(Units: ¥ billion)



Highlight ①

Despite drug price revisions (in the 6% range for KYORIN Pharmaceutical), net sales rose ¥1.4 billion year on year, and gross profit increased ¥0.9 billion.

Highlight ②

R&D expenses increased about ¥2.0 billion from a year ago, reflecting the progress of development pipelines, for which the Company is making utmost efforts.

Highlight ③

SG&A expenses excluding R&A Expenses were reduced. (The ratio of SG&A expenses, excluding R&D expenses, declined 2.8 percentage points.)

Consolidated Financial Results for the First Quarter Ended June 30, 2010



(Units: ¥ billion)

	First Quarter June 30, 2009	First Quarter June 30, 2010	Change
Net sales (total)	23.3	24.7	+1.4
Ethical drugs business	22.5	24.0	+1.5
◆Sales of new ethical drugs	19.5	20.8	+1.3
○Japan	18.9	20.2	+1.3
○Overseas	0.6	0.6	+0.0
◆Generic drugs	1.8	2.1	+0.3
◆Over-the-counter drugs	1.2	1.0	△0.1
Healthcare business	0.8	0.7	△0.1
◆Skin care	0.8	0.7	△0.1
Operating income	3.2	2.2	△0.9
Ordinary Income	3.4	2.4	△1.0
Net income	2.0	1.8	△0.2

(Note 1) The results for the first quarter under review are compared with results for the first quarter of the previous fiscal year that have been rearranged by a convenient method.
(Note 2) The products and services included in the Consumer Healthcare Business are different from those in the disclosed results for the fiscal year ended March 2010 and earlier periods.

■ Net sales	¥24.7billion	Change (+1.4)
◆ Ethical drugs business	¥24.0billion	(+1.5)
● Sales of new ethical drugs in Japan	¥20.8billion	(+1.3)
10.3(1Q)(results)	11.3(1Q)(results)	
· Kipres	6.6 ⇒ 7.4	(+ 0.8)
· Mucodyne	5.1 ⇒ 5.6	(+ 0.5)
· Pentasa	4.8 ⇒ 5.0	(+ 0.2)
· Uritos	0.8 ⇒ 1.3	(+ 0.5)
● Sales of new ethical drugs in Overseas	¥0.6billion	(+0)
0.6 ⇒ 0.5		(△0.1)
● Generic drugs	¥2.1billion	(+0.3)
* Sales increased on main products.		
● Over-the-counter drugs	¥1.0billion	(△0.1)
◆ Healthcare Business	¥0.7billion	(△0.1)
● Skin care	¥0.7billion	(△0.1)
■ Operating income	¥2.2billion	(△0.9)
◆ The operating income margin decreased 4.6 percentage points , to 9.0%		
● Cost of sales ratio is almost level	(37.2%⇒37.2%)	
Factors for increase: price revision		
Factors for decrease : Sales of in-house products, which have low costs of sales, increased. The cost of sales ratio of KYORIN Remedio declined		
● R&D ratio : up 3.3 points	(9.4%⇒16.8%)	
* ¥2.2billion⇒¥4.1billion		
The progress of development pipelines (KRP-108 Ph2b ended)		
● SG&A expenses ratio	(39.8%⇒37.0%)	
(excluding R&D expenses): down 2.8 points		
Factors for decrease: A reduction in general expenses		
■ Net income	¥1.8billion	(△0.2)

Main Product Sales Update

(Units: ¥ billion)

Product name		Interim term		Full term		First quarter (April 1, 2010 to June 30, 2010)				
		FY09 (results)	FY10 (forecast)	FY09 (results)	FY10 (forecast)	FY09 (results)	FY10 (results)	YoY change (%)	Progress to Interim term forecast(%)	Progress to Full term forecast(%)
Sales of new ethical drugs (Japan)	Kipres (LT receptor antagonist)	12.7	13.7	29.2	31.4	6.6	7.4	11.6%	54.1%	23.5%
	Mucodyne (Mucoregulant)	9.3	9.5	20.9	21.4	5.1	5.6	9.5%	58.3%	26.0%
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	9.7	9.8	19.4	20.1	4.8	5.0	3.2%	50.7%	24.7%
	Uritos (Kyorin) (Overactive bladder)	1.6	2.2	3.7	5.1	0.8	1.3	58.3%	57.3%	24.8%
	Ketas (For bronchial asthma and cerebrovasculas disorders)	2.3	2.2	4.6	4.0	1.1	1.0	△10.8%	45.9%	25.4%
Sales of new ethical drugs (over seas)	Gatifloxacin (Bulk · Royalty)	1.1	1.0	2.2	1.3	0.6	0.5	△9.7%	50.3%	39.8%
Over-the- counter drugs	Milton (Disinfectant)	1.0	1.0	1.9	2.1	0.5	0.5	△2.6%	44.3%	22.1%

Main R&D Activities① (July 30 , 2010 Release)

Ph II～Application

Stage		Compound/ Code	Therapy area/ Action	Origin	Features	Comments
Domestic	Overseas					
Ph III (12/2009)		PENTASA Tablets	Ulcerative colitis	Ferring Pharma- ceuticals	New dosage regimen for ulcerative colitis in the remission phase (once a day)	
Ph II (3/2005)	(Eisai: PhIII)	AS-3201 (Tablets)	Diabetic neuropathy	Dainippon Sumitomo	Aldose reductase inhibitor to reduce the sorbitol accumulation in the cell, and improve diabetic neuropathy	Co-development with Dainippon Sumitomo Ph II b (9/2007)
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.	Ph II b in overseas (11/2009) Ph II b in domestic completed (3/2010)
Ph II (8/2008)	US: Abbott NDA filed (3/2009) Europe: Mundipharma MAA submitted (3/2010)	KRP-108	anti-asthmatic	Skye Pharma PLC	An ICS/LABA combination product, which offers better compliance and convenience to the patients.	License Agreement with SkyePharma (4/2008) Ph II completed in domestic (4/2010)

Other Comments

※Orally Disintegrating Tablet of Immidafenasin (INN),
a Drug for Overactive Bladder

: Application(12/2009)

Main R&D Activities② (July 30 , 2010 Release)

POC Project (Pre-clinical~Ph I)

Stage		Compound/ Code	Therapy area/ Action	Origin	Features	Comments
Domestic	Overseas					
Ph I in preparation	Ph I (7/2007)	KRP-203	Transplantatio n and autoimmune diseases treatment	In-house	An immunosuppressant with novel mechanism called 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)
	Ph I in preparation	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.	

In licensing

Stage		Compound/ Code	Therapy area/ Action	Origin	Features	Comments
Domestic	Overseas					
Ph-II in preparation	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 through mainly its two pharmacological properties: 1)NMDA antagonistic activity and 2)Nicotinic acetylcholine antagonistic activity	License Agreement with Merz (11/2009) Ph I clinical trial in Japanese (single dose PK) in US completed by Merz (03/2010)

Main R&D Activities③ (July 30, 2009 Release)

Licensing development

Product name・Code	Stage	Licensee・Collaborative research	Therapy area/Action	Origin	Comments
Alphagan/ Alphagan P	Domestic Ph III (7/2007)	Senju Seiyaku	Glaucoma	Allergan (US)	<ul style="list-style-type: none"> •Licensed from Allergan (Cross license of gatifloxacin ophthalmic solution) •License-out to Senju (5/2004)
Ketas	Overseas Ph II (8/2005)	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.
KCA-757	Overseas Ph III (Anti-bronchial Asthma: 11/2006) Ph II/III (Interstitial cystitis: 5/2005)	MediciNova (US)	Anti-bronchial asthma and Interstitial cystitis agent	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 •Interstitial cystitis: Results of Ph II/III was reported in January 2007 and ceased development •Bronchial asthma: Clinical trial oversea was discontinued.
KRP-203	Overseas Ph I (7/2007)	Novartis (Switzerland)	Transplantation and autoimmune diseases treatment	In-house	An immunosuppressant with novel mechanism called 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 immunosuppressants.

Reference

Segment information for the First Quarter Ended June 30, 2010

Sales, profit or loss of each report segment

(Units: ¥ billion)

	Sales		Profit	
	金額	Year on Year	金額	Year on Year
Net sales (total)	24.7	+1.4	2.2	△0.9
Ethical drugs business	24.0	+1.5	2.1	—
◆Sales of new ethical drugs	20.8	+1.3		
○Japan	20.2	+1.3		
○Overseas	0.6	+0		
◆Generic drugs	2.1	+0.3		
◆Over-the-counter drugs	1.0	△0.1		
Healthcare Business	0.7	△0.1	△0	—
◆Skin care	0.7	△0.1		
Amount of adjustment	—		0.1	—

(Note 1) Starting the first quarter under review, 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.

(Note 2) The results for the first quarter under review are compared with results for the previous fiscal year, which have been modified using the most reasonable method.

Consolidated Financial Results for the First Quarter Ended June 30, 2010



	Interim term		Full term		First quarter (April 1, 2010 to June 30, 2010)					
	FY09 (results)	FY10 (forecast)	FY09 (results)	FY10 (forecast)	FY09 (results)	FY10 (results)	Change	YoY change (%)	Progress to interim term forecast (%)	Progress to full term forecast (%)
Sales	45,714	46,500	99,764	100,300	23,289	24,655	+1,365	5.9%	53.0%	24.6%
◆ Ethical drugs business	44,115	44,791	96,421	96,567	22,485	23,955	+1470	6.5%	53.5%	24.8%
Sales of new ethical drugs	38,011	38,894	82,395	84,339	19,503	20,794	+1,291	6.6%	53.5%	24.7%
Japan	36,733	37,575	79,766	82,560	18,910	20,167	+1,257	6.6%	53.7%	24.4%
Overseas	1,278	1,319	2,629	1,779	592	626	+34	5.7%	47.5%	35.2%
Generic drugs	3,584	3,611	8,642	7,647	1,829	2,145	+316	17.3%	59.4%	28.1%
Over-the- counter drugs	2,519	2,286	5,384	4,576	1,153	1,015	△138	△12.0%	44.4%	22.2%
◆ Consumer healthcare business	1,599	1,751	3,342	3,733	803	699	△104	△13.0%	39.9%	18.7%
Skin care	1,599	1,751	3,342	3,733	803	699	△104	△13.0%	39.9%	18.7%
Operating income	4,569	2,500	13,261	12,700	3,156	2,216	△939	△29.8%	88.6%	17.4%
Ordinary income	5,172	2,900	14,234	13,400	3,417	2,421	△996	△29.2%	83.5%	18.1%
Net income	3,293	1,700	8,848	8,500	1,976	1,799	△177	△9.0%	105.8%	21.2%

(Note) The results in the first quarter under review and results forecasts for the first half and full year are compared with results for the previous fiscal year, which have been rearranged by a convenient method.

Actual and Forecast of Main Subsidiary Companies

(Units: ¥ billion)

KYORIN pharmaceutical	3 / 10 (results)	3 / 11 (forecast)	First quarter 3 / 10 (results)	First quarter 3 / 11 (results)
Sales	85.3	87.3	20.2	21.5
Operating profit	13.1	12.3	3.4	2.0
Net profit	9.5	8.4	2.5	1.7

KYORIN Rimedio	1 / 10 (results)	3 / 11 (forecast)	First quarter 1 / 10 (results)	First quarter 3 / 11 (results)
Sales	10.1	8.9	2.1	2.4
Operating profit	0.4	0.2	0	0.2
Net profit	0.4	0.1	0.1	0.2

Dr.Program	3 / 10 (results)	3 / 11 (forecast)	First quarter 3 / 10 (results)	First quarter 3 / 11 (results)
Sales	3.3	3.7	0.8	0.7
Operating profit	△0.1	0.2	△0.2	△0
Net profit	△0.1	0.2	△0.2	△0