# First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2014

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July 30, 2013 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, 2014



Units: millions of yen	First quarter Jun / 2010	First quarter Jun / 2011	First quarter Jun / 2012	First quarter Jun / 2013	YoY change (%)	Interim term Sep / 2013 (forecast)	YoY change (%)	Year ending Mar / 2014 (forecast)	YoY change (%)
Net sales	24,655	24,809	25,422	26,239	+3.2%	51,500	+7.4%	113,000	+5.6%
Operating income	2,216	4,100	4,080	4,465	+9.4%	6,700	+6.9%	18,600	+3.6%
Ordinary income	2,421	4,300	4,351	4,681	+7.6%	7,000	+5.9%	19,200	+2.8%
Net income	1,799	2,697	2,838	2,996	+5.6%	4,600	+7.1%	12,700	+2.2%

### First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2014

**[Net Sales]** Sales of ethical drug and generic drug increased year on year. And sales of KYORIN Pharmaceutical Facilities which commenced operations on Oct 1<sup>st</sup>/2012 contributed to increase of net sales. As a result, consolidated net sales increased 3.2% year on year, to ¥26.2bln.

**[Income]** While SG&A expenses increased, gross profit rose due to the decrease of cost of sales ratio. Consequently, operating income rose 9.4% to ¥4.5bln, net income rose 5.6% to ¥3.0bln year on year.

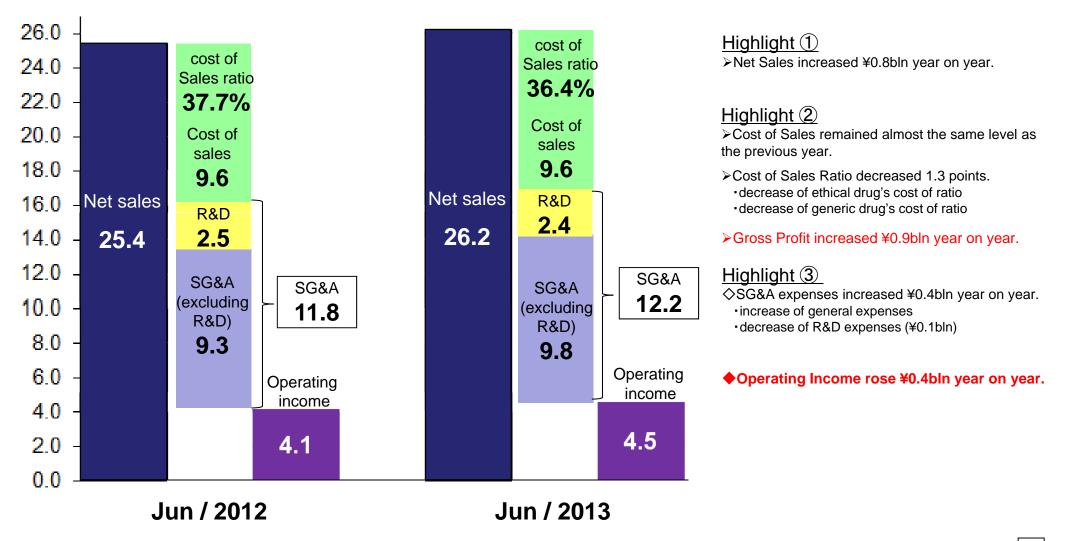
#### Consolidated Financial Results for the Fiscal Year Ending March 31, 2014(forecast)

The results forecasts for the first half and the full year announced on May 9, 2013 remain unchanged. (Progress compared with the forecast for the first half: net sales: 51.0%; operating income: 66.6%)

## **Highlights of Business Performance**



(Units: ¥ billion)



# **Consolidated Financial Results**

## for the first Quarter ending March 31, 2014



Year on Year

#### Jun/2012 Jun/2013 (¥ billion) change 25.4 26.2 +0.8Net Sales **Ethical drugs** 25.8 +0.924.9 **Business** ♦ Sales of new 21.3 22.2 +0.9ethical drugs +1.021.6 20.6 Japan -0.10.7 0.6 Overseas 2.6 2.7 +0.1♦ Generic drugs ♦Over-the-0.9 1.0 -0.1counter drugs Healthcare -0.1(Skin care) 0.5 0.4 **Business** Operating 4.5 +0.44.1 Income Ordinary 4.7 +0.34.4 Income 2.8 3.0 Net Income +0.2

■Net Sales	¥26.2bln	(+ 0.8)
Ethical drugs business	¥25.8bln	(+ 0.9)
● Sales of new ethical dru Jun/2012⇒Jun/201	-	(+ 1.0)
· Kipres $8.8 \Rightarrow 8.7$ · Uritos $1.9 \Rightarrow 1.9$ · Mucodyne $4.6 \Rightarrow 4.5$ · Pentasa $4.5 \Rightarrow 4.7$	(-0.1) (+0.2)	
<ul> <li>KYORIN Pharmaceutical Faciliti</li> <li>Sales of new ethical drugs in O</li> <li>Gatifloxacin 0.7 ⇒ 0.5</li> </ul>		(-0.1)
<ul> <li>Sales of Generic drugs</li> <li>Health insurance pharmacy mail</li> </ul>	¥2.7bln	(+ 0.1)
Sales of Over-the-counter drug		(-0.1)
Healthcare (Skin care) Busin	ess ¥0.4bln	( - 0.1)
Sales declined at Dr. Program		( - 0.1)
Operating Income	¥4.5bln	(+ 0.4)
◆Operating Income margin	rose 1.0 percentage points	<u>s to 17.0%</u>
●Cost of Sales Ratio : 36.4%	1 01	
	ratio : increase of royalty (licensing o f ratio : increase of sales (strategic,su	
	0.6 percentage points (9.7%	
·¥2.5bln⇒¥2.4bln		,
●SG&A Ratio (excluding R& ·¥9.3bln⇒¥9.8bln	. , .	9 percentage points
<b>-</b> ,	(head office relocation expense , p	
Net Income	¥3.0bln	(+ 0.2)



#### (Units: ¥ billion)

			n term	Full term			First quarter (April 1 to June 30)					
Product name		FY2012 (results)			FY2012 (results)	FY2013 (results)	YoY change (%)	Progress to Interim term forecast(%)	Progress to Full term forecast(%)			
	Kipres (LT receptor antagonist)	16.3	17.7	39.6	40.8		8.8	8.7	-1.0%	48.9%	21.2%	
Sales of	Mucodyne (Mucoregulant)	8.3	8.0	19.1	18.7		4.6	4.5	-3.0%	56.0%	24.0%	
new ethical drugs	Pentasa (Ulcerative colitis and Crohn's disease treatment)	9.0	9.3	17.6	18.6		4.5	4.7	+2.4%	49.5%	25.0%	
(Japan)	Uritos(Kyorin) (Overactive bladder)	3.6	3.9	7.5	8.4		1.9	1.9	+2.3%	49.1%	22.9%	
	Ketas (For bronchial asthma and cerebrovasculas disorders)	1.5	1.3	3.0	2.7		0.8	0.8	-1.5%	56.6%	28.4%	
Sales of new ethical drugs (over seas)	Gatifloxacin (Bulk · Royalty)	0.9	0.9	1.6	1.6		0.7	0.5	-19.5%	55.3%	31.9%	
Over-the- counter drugs	Milton (Disinfectant)	1.0	1.0	2.0	2.1		0.5	0.5	-4.9%	44.3%	21.9%	

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

# Actual and Forecast of Main Subsidiary Companies Kyorin



				(Units: ¥ billion)
KYORIN pharmaceutical	First quarter Jun/2012(results)	First quarter Jun/2013(results)	FY 2012 (results)	FY2013 (forecast)
Sales	23.0	23.3	95.9	100.0
Operating profit	4.1	4.1	17.1	17.7
Net profit	2.9	3.0	11.9	12.4

KYORIN Rimedio	First quarter Jun/2012(results)	First quarter Jun/2013(results)	FY 2012 (results)	FY2013 (forecast)
Sales	2.7	2.9	10.4	11.5
Operating profit	0.0	0.2	0.4	0.4
Net profit	0.0	0.1	0.5	0.2

Dr. Program	First quarter Jun/2012(results)	First quarter Jun/2013(results)	FY 2012 (results)	FY2013 (forecast)	
Sales	0.5	0.4	1.9	1.7	
Operating profit	-0.1	0.1	-0.2	0.1	
Net profit	-0.1	0.1	-0.3	0.1	

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## Main R&D Activities -1 (July 30, 2013 Release)



## Ph III ~ Application submitted

Changes from the previous announcement (May 9, 2013)

Stage		Stage Compound/		Origin	Features	Comments	
Japan	Overseas	Code	area/Action	Ongin	realules	Comments	
Application submitted (9/2012)	(US) SkyePharma : Application submitted (3/2009) (Europe) Mundipharma :Launched(9/2012)	KRP-108 (Inhalant)	Anti- asthmatic	SkyePharma PLC	An ICS/LABA combination product, which offers better compliance and convenience to the patients	<ul> <li>License agreement with SkyePharma (4/2008)</li> <li>Domestic Ph II completed (4/2010)</li> <li>Ph II completed(3/2012)</li> </ul>	
PhIII (9/2012)	(Europe) Almirall : Launched(9/2012) (US) Forest Pharmaceuticals : Launched (12/2012)	KRP-AB1102 (Inhaled drug)	Chronic Obstructive Pulmonary Disease (COPD)	Almirall	<ul> <li>New Chemical Entity: Aclidinium Bromide</li> <li>Long Acting Muscarinic Agonist (LAMA)</li> <li>Twice Daily administration</li> <li>Onset of Action on the first day Genuair®</li> <li>1) Designed with a feedback system, which through a 'colored control window' and an audible click helps confirm that the patient has inhaled correctly</li> <li>2) Counter for remaining doses</li> <li>3) Safety features such as an anti-double-dosing mechanism and an end-of-dose lock-out system to prevent use of an empty inhaler</li> </ul>	License agreement with Almirall (2/2011)	
PhⅢ (4/2013)		KIPRES (Chewable Oral Granules)	Bronchial Asthma	Merck	For pediatric patient : Allergic Rhinitis	<ul> <li>Additional indication</li> <li>Co-development with MSD K.K.</li> </ul>	

\*Pentasa Suppository, a treatment for ulcerative colitis: launched June/2013

\*Uritos ,an overactive bladder drug : launched in Korea July/2013 (Chong Kun Dang Pharmaceutical Corp.)

## Main R&D Activities -2 (July 30, 2013 Release)



### POC Project (Pre-clinical ~ Ph II)

Changes from the previous announcement (May 9, 2013)

Stage		Compound/	Compound/		Factures	Comments	
Japan	Overseas	Code	Therapy area/Action	Origin	Features	Comments	
Ph II (5/2012)	(Europe & US) Almirall: Ph Ⅲ (US) Forest Laboratories : Ph Ⅲ	KRP-AB1102F (Fixed dose combination inhaled drug)	Chronic Obstructive Pulmonary Disease (COPD)	Almirall	Combination of aclidinium bromide with the long acting beta agonist formoterol : This combination is aimed at providing higher efficacy than each component alone,as well as the improved convenience of having the two products in the same easy to use inhalation device. This is currently in phase III clinical development.		
Ph II (8/2011)	PhⅢ 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)	
Ph II (3/2013)	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 (8/2011)		KRP-AM1977X (Oral agent)	New quinolone synthetic antibacterial agent	In-house	<ol> <li>Superior ability to combat drug-resistant gram- positive bacteria (incl. MRSA)</li> <li>Outstanding ADME (oral absorption, tissue</li> </ol>		
Ph I (7/2012)		KRP-AM1977Y (Injection)	New quinolone synthetic antibacterial agent	In-house	migration) ③High degree of safety expected since safety hurdles cleared prior to clinical trials		



## Sales, Profit or Loss of each report segment

(Units:¥ billion)	Sales	Year on Year	Profit	Year on Year
total	26.2	+0.8	4.5	+0.4
Ethical drugs business	25.8	+0.9	4.3	+0.2
Sales of new ethical drugs	22.2	+0.9		
●Japan	21.6	+1.0		
●Overseas	0.6	-0.1		
♦Generic drugs	2.7	+0.1		
Over-the-counter drugs	0.9	-0.1		
Healthcare(Skincare) business	0.4	-0.1	0.1	+0.2
Amount of adjustment		—	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 ending March 31, 2014



	Interir	n term	Full term				First	quarter (A	pril 1 to Jun	e 30)	
(Units: ¥million)	FY2012 (results)	FY2013 (forecast)	FY2012 (results)	FY2013 (forecast)		FY2012 (results)	FY2013 (results)	Change	YoY change (%)	Progress to interim term forecast (%)	Progress to full term forecast (%)
Sales	47,954	51,500	107,031	113,000		25,422	26,239	+816	+3.2%	51.0%	23.2%
Ethical drugs business	47,034	50,800	105,162	111,300		24,921	25,801	+880	+3.5%	50.8%	23.2%
♦Sales of new ethical drugs	39,684	43,500	90,686	95,600		21,331	22,215	+883	+4.1%	51.1%	23.2%
●Japan	38,661	42,300	88,286	93,500		20,586	21,582	+995	+4.8%	51.0%	23.1%
● Overseas	1,023	1,200	2,400	2,100		745	633	-112	-15.1%	52.8%	30.2%
♦Generic drugs	5,056	5,100	10,095	11,100		2,635	2,686	+51	+1.9%	52.7%	24.2%
♦OTC drugs and others	2,292	2,200	4,379	4,600	-	953	899	-54	-5.7%	40.9%	19.6%
Consumer healthcare business	920	700	1,869	1,700		501	438	-63	-12.7%	62.6%	25.8%
Operating income	6,269	6,700	17,948	18,600		4,080	4,465	+385	+9.4%	66.6%	24.0%
Ordinary income	6,609	7,000	18,676	19,200		4,351	4,681	+330	+7.6%	66.9%	24.4%
Net income	4,295	4,600	12,422	12,700		2,838	2,996	+158	+5.6%	65.2%	23.6%