# First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2016

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July 30, 2015 **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, 2016



Units: millions of yen	First quarter Jun / 2012	First quarter Jun / 2013	First quarter Jun / 2014	First quarter Jun / 2015	YoY change (%)	Interim term Sep / 2015 (forecast)	YoY change (%)	Year ending Mar / 2016 (forecast)	YoY change (%)
Net sales	25,422	26,239	26,397	26,567	+0.6%	54,400	+6.4%	120,200	+6.3%
Operating income	4,080	4,465	3,575	2,173	-39.2%	3,800	-17.2%	16,000	+8.6%
Ordinary income	4,351	4,681	3,847	2,316	-39.8%	4,000	-18.3%	16,300	+5.2%
Net income	2,838	2,996	2,681	1,757	-34.5%	2,600	-25.6%	11,500	-4.7%

#### First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2016

#### [Net Sales]

Sales growth was driven by year on year increased in ethical drug sales(growth of our main product Flutiform), overall net sales increased 0.6% year on year to ¥26.6bln.

#### [Income]

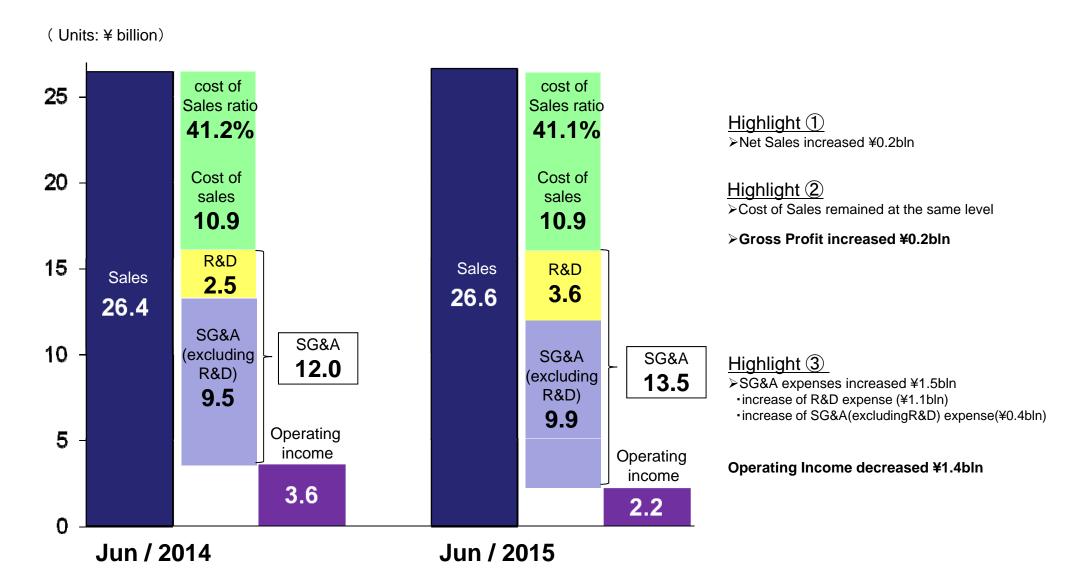
Cost of sales ratio remained at the same level as last year, gross profit increased ¥0.1bln year on year. At the other side, SG & A expenses increased in R&D expenses. Consequently, operating income decreased 39.2% to ¥2.1bln, net income decreased 34.5% to ¥1.7bln year on year.

#### Consolidated Financial Results for the Fiscal Year Ending March 31, 2016(forecast)

The results forecasts for the first half and the full year announced on May 13, 2015 remain unchanged. (Progress compared with the forecast for the first half: net sales: 48.8%; operating income: 57.2%)

## **Highlights of Business Performance**





## **Consolidated Financial Results**for the first Quarter ending March 31, 2016



(¥ billion)	Jun/2014	Jun/2015	change
Net Sales	26.4	26.6	+0.2
Ethical drugs Business	26.1	26.3	+0.2
◆Sales of new ethical drugs  ●Japan	21.2 21.0	21.4 21.2	+0.2 +0.2
● Overseas	0.2	0.2	0
<b>♦</b> Generic drugs	4.0	3.8	-0.2
♦Over-the- counter drugs	0.9	1.0	+0.1
Healthcare (Skin care) Business	0.3	0.3	0
Operating Income	3.6	2.2	-1.4
Ordinary Income	3.8	2.3	-1.5
Net Income	2.7	1.8	-0.9

				Year on Yea
■Net Sales			¥26.6bln	(+ 0.2)
♦Ethical drugs	business		¥26.3bln	(+ 0.2)
	w ethical drug	_	¥21.2bln	(+ 0.2)
<ul><li>Kipres</li><li>Mucodyne</li><li>Pentasa</li><li>Uritos</li><li>Flutiform</li></ul>	$9.1 \Rightarrow 9.5$ $3.4 \Rightarrow 3.2$ $4.3 \Rightarrow 4.1$ $1.6 \Rightarrow 1.9$ $0.4 \Rightarrow 1.5$	(-0.2) (-0.2) (+0.3)	) 	
	hical drugs in O		¥0.2bln	( 0)
	alth insurance ph	armacy m	<b>¥3.8bln</b> narket's sales	(-0.2)
_	ontract manufactı <b>he-counter dru</b> ç	•	¥1.0bln	(+ 0.1)
♦Healthcare (Sk	n care) Busin	ess	¥0.3bln	( 0)
■Operating Inc	ome		¥2.2bln	(-1.4)
♦Operating Inco	ne margin dec	creased	5.3 percentage po	oints to 8.2%
●Cost of Sales	Ratio : decrea	ased 0.1	percentage point	s (41.2%⇒41.1%)
●R&D Ratio : i	ncreased 4.3 p	percenta	ige points (9.3%≕	·13.6%)
	6bln +¥1.1bln	. •		
●SG&A Ratio (	excluding R&	D exper	ises) : increased 1	.1 percentage poin
•¥9.5bIn⇒¥9.9 increase of pa				(36.0%⇒37.
■Net Income			¥1.8bln	(-0.9)

## Actual and Forecast of Main Subsidiary Companies Kyorin



( Units: ¥ billion )

KYORIN		
pharmaceutical		
Sales		
Operating income		
Net income		

First quarter Jun/2014(results)	First quarter Jun/2015(results)	
22.7	23.3	
2.9	1.6	
2.4	1.5	

FY 2014 (results)	FY2015 (forecast)
98.5	105.3
12.2	13.3
10.4	10.0

KYORIN Rimedio	
Sales	
Operating income	
Net income	

First quarter Jun/2014 (results)	First quarter Jun/2015 (results)
4.1	3.8
0.6	0.4
0.4	0.3

FY 2014 (results)	FY2015 (forecast)
16.4	18.5
2.1	2.3
1.5	1.6

Dr. Program		
Sales		
Operating income		
Net income		

First quarter Jun/2014(results)	First quarter Jun/2015(results)	
0.3	0.3	
0.0	0.0	
0.0	0.0	

FY 2014 (results)	FY2015 (forecast)
1.4	1.6
0.0	0.0
0.0	0.0

## **Main Product Sales Update**



( Units: ¥ billion )

	Product name		Interim term		Full term		First quarter (April 1 to June 30)					
			Sep/2015 (forecast)	Mar/2015	Mar/2016 (forecast)		Jun/2014	Jun/2015	YoY change (%)	Progress to Interim term forecast(%)	Progress to Full term forecast(%)	
Sales of new ethical drugs	Kipres (LT receptor antagonist)	17.4	18.1	41.2	41.8		9.1	9.5	+4.7%	52.2%	22.6%	
	Mucodyne (Mucoregulant)			3.2	-5.6%	60.2%	26.9%					
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	8.6	8.4	17.2	17.1	1 4.3		4.1	-5.5%	48.0%	23.7%	
(Japan)	Uritos (Kyorin) (Overactive bladder)	3.4	3.8	7.3	7.9		1.6	1.9	+18.5%	49.5%	23.7%	
	Flutiform (Anti-asthmatic)	0.9	4.1	3.6	10.3		0.4	1.5	+249.7%	37.4%	14.9%	
Sales of new ethical drugs (over seas)	Gatifloxacin (Bulk • Royalty)	0.1	0.1	0.6	0.4		0.1	0.1	-26.7%	56.8%	19.7%	
Over-the- counter drugs	Milton (Disinfectant)	1.0	0.9	2.0	2.0		0.4	0.5	+8.1%	48.8%	24.2%	

## Main R&D Activities -1 (as of July 30 2015)



### Ph III ~ Application submitted

	Stage		Thorany area/Action	Origin	Features	Comments	
Japan	Overseas	Code	Therapy area/Action	Origin	reatules	Comments	
PhⅢ (13年8月)	(Europe) AstraZeneca :Launched (1/2015) (US) AstraZeneca : PhⅢ	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.		
PhⅢ (1/2015)	Ph II clinical trial end Merck & Co.,	KRP-114V	Overactive bladder	Merck & Co.,	KRP-114V is expected to improve urinary frequency through stimulation of the beta 3 receptor in bladder which improves bladder muscle relaxation.	License agreement with Merck & Co., Inc.,(7/2014)	
PhⅢ (4/2015)	KRP-AM1977X (Oral agent) New quinolone synthetic antibacterial agent		In-house	Superior ability to combat drug-resistant gram- positive bacteria (incl. MRSA)     Outstanding ADME (oral absorption, tissue migration)     High degree of safety expected since safety hurdles cleared prior to clinical trials			

## Main R&D Activities -2 (as of July 30 2015)



### POC Project (Ph I ~ Ph II)

\*Changes from the previous announcement(May 13 2015)

Stage		Compound/	The representation	Ovietie	Factoria	Comments	
Japan	Overseas	Code	Therapy area/Action	Origin	Features	Comments	
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)	License out : Novartis Ph II (POC) (12/2010)	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 II (6/2014)		KRP-AM1977Y (Injection)	New quinolone synthetic antibacterial agent	In-house	Superior ability to combat drug-resistant gram- positive bacteria (incl. MRSA)     Outstanding ADME (oral absorption, tissue migration)     High degree of safety expected since safety     hurdles cleared prior to clinical trials		
<b>※Ph I , II</b> (7/2015)	(US) Momotaro-Gene prostate cancer (5/2014)	Ad-SGE-REIC	malignant pleural mesothelioma	Okayama University	A gene-therapy product using a novel tumor suppressor gene of reduced expression in immortalized cells/ Dickkopf-3 (REIC/Dkk-3), which was discovered by researchers from Okayama University, as a therapeutic gene. It is expected to have direct effect on primary tumor lesions and indirect effect on metastatic tumor lesions as a genetherapy product that simultaneously induces tumor cell-selective apoptosis and the activation of antitumor immunity respectively.	Adopted to Next generation Technology Transfer Program (NexTEP) (6/2014)	

### for reference

Stage	Compound/ Code	Therapy area/Action	Features	Comments	
under development by MSD K.K. (PhⅢ)	Desloratadine	allergic rhinitis, hives, itching resulting from skin diseases (eczema/dermatitis, pruritus cutaneous)	second generation histamine H1-receptor antagonist	Co-Marketing Agreement for Japan with MSD K.K. affiliate (11/2014)	



## Reference

## **Segment information** for the first Quarter Ending March 31, 2016



### Sales, Profit or Loss of each report segment

(Units:¥ billion)	Sales	Year on Year	Profit	Year on Year
total	26.6	+0.2	2.2	-1.4
Ethical drugs business	26.3	+0.2	2.1	-1.4
◆Sales of new ethical drugs	21.4	+0.2		
●Japan	21.2	+0.2		
● Overseas	0.2	0		
♦Generic drugs	3.8	-0.2		
♦Over-the-counter drugs	1.0	+0.1		
Healthcare(Skincare) business	0.3	0	0.0	0
Amount of adjustment	_	_	0.1	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, 2016**



	Interin	n term	Full term		First quarter (April 1 to June 30)						
(Units: ¥million)	Sep/2014	Sep/2015 (forecast)	Mar/2015	Mar/2016 (forecast)	Jun/2014	Jun/2015	Change	YoY change (%)	Progress to interim term forecast (%)	Progress to full term forecast (%)	
Sales	51,112	54,400	113,121	120,200	26,397	26,567	+170	+0.6%	48.8%	22.1%	
Ethical drugs business	50,518	53,700	111,771	118,600	26,093	26,251	+158	+0.6%	48.9%	22.1%	
◆Sales of new ethical drugs	40,755	42,900	92,111	95,700	21,206	21,439	+233	+1.1%	50.0%	22.4%	
●Japan	40,422	42,500	91,079	94,700	20,981	21,249	+268	+1.3%	50.0%	22.4%	
● Overseas	332	400	1,032	1,000	224	189	-35	-15.6%	47.3%	18.9%	
♦Generic drugs	7,790	8,700	15,477	18,200	3,973	3,821	-152	-3.8%	43.9%	21.0%	
♦OTC drugs and others	1,972	2,000	4,183	4,500	913	990	+77	+8.4%	49.5%	22.0%	
Consumer healthcare business	593	700	1,349	1,600	303	316	+13	+4.3%	45.1%	19.8%	
Operating income	4,587	3,800	14,737	16,000	3,575	2,173	-1,402	-39.2%	57.2%	13.6%	
Ordinary income	4,898	4,000	15,490	16,300	3,847	2,316	-1,531	-39.8%	57.9%	14.2%	
Net income	3,495	2,600	12,064	11,500	2,681	1,757	-924	-34.5%	67.6%	15.3%	