# First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2015

- 1. Overview of consolidated results
- 2. Main Product Sales Update
- 3. Development pipelines
- [Reference]
- 4. Segment information
- 5. Consolidated Financial

July 29, 2014 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, 2015



Units: millions of yen	First quarter Jun / 2011	First quarter Jun / 2012	First quarter Jun / 2013	First quarter Jun / 2014	YoY change (%)	Interim term Sep / 2014 (forecast)	YoY change (%)	Year ending Mar / 2015 (forecast)	YoY change (%)
Net sales	24,809	25,422	26,239	26,397	+0.6%	51,300	+0.9%	112,200	+0.7%
Operating income	4,100	4,080	4,465	3,575	-19.9%	5,500	-11.5%	15,800	-10.3%
Ordinary income	4,300	4,351	4,681	3,847	-17.8%	5,700	-12.7%	16,300	-10.8%
Net income	2,697	2,838	2,996	2,681	-10.5%	3,900	-11.3%	11,300	-6.0%

First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2015

#### [Net Sales]

Overall net sales increased 0.6% year on year to ¥26.4bln. Sales growth was driven by year on year increased in generic drug sales, despite lower sales in the ethical drug.

#### [Income]

Cost of sales ratio increased due to the drug price revision, increase of generic drugs, decrease of overseas ethical drug, gross profit decreased ¥1.1bln year on year. SG & A expenses fell given a decrease in general expenses. Consequently, operating income decreased 19.9% to ¥3.6bln, net income decreased 10.5% to ¥2.7bln year on year.

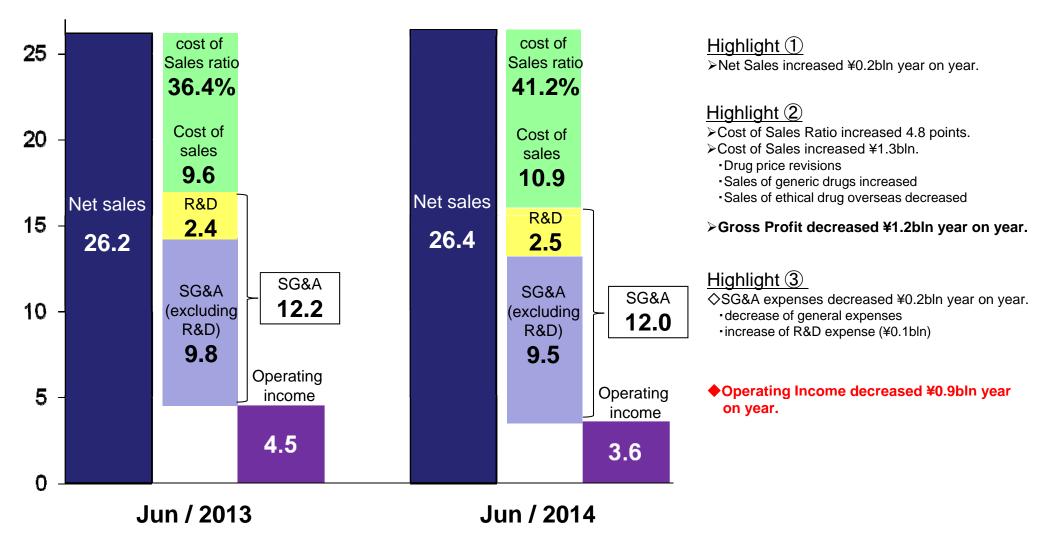
#### **Consolidated Financial Results for the Fiscal Year Ending March 31, 2015(forecast)**

The results forecasts for the first half and the full year announced on May 9, 2014 remain unchanged. (Progress compared with the forecast for the first half: net sales: 51.5%; operating income: 65.0%)

# **Highlights of Business Performance**



(Units: ¥ billion)



# **Consolidated Financial Results**

#### for the first Quarter ending March 31, 2015



#### Year on Year

(¥ billion)	Jun/2013	Jun/2014	change
Net Sales	26.2	26.4	+0.2
Ethical drugs Business	25.8	26.1	+0.3
<ul> <li>Sales of new ethical drugs</li> <li>Japan</li> <li>Overseas</li> <li>Generic drugs</li> <li>Over-the- counter drugs</li> <li>Healthcare (Skin care)</li> </ul>	22.2 21.6 0.6 2.7 0.9 0.4	21.2 21.0 0.2 4.0 0.9 0.3	-1.0 -0.6 -0.4 +1.3 0.0 -0.1
Business Operating Income	4.5	3.6	-0.9
Ordinary Income	4.7	3.8	-0.9
Net Income	3.0	2.7	-0.3

Net Sales		¥26.4bln	(+ 0.2)
Ethical drugs b	usiness	¥26.1bln	(+ 0.3)
● Sales of new e	ethical drugs 2013⇒Jun/2014	¥21.0bln	(-0.6)
Mucodyne 4     Pentasa 4	$\begin{array}{rrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrr$		
	al drugs in Overseas $0.5 \Rightarrow 0.1  (-0.4)$	<b>¥0.2bln</b>	(-0.4)
Sales of Generic d	•	¥4.0bln	(+ 1.3)
-		es and Contract manufactu	•
Sales of Over-the-	counter drugs	¥0.9bln	( 0.0)
Healthcare (Skin o	care) Business	¥0.3bln	(-0.1)
Operating Incom	10	¥3.6bln	(-0.9)
Operating Income	margin decreased	3.5 percentage point	<u>s to 13.5%</u>
	s (in the 3%range for KY0 ugs increased.	percentage points (	36.4%⇒41.2%)
<ul> <li>Drug price revisions</li> <li>Sales of generic dru</li> <li>Sales of Gatifloxaci</li> <li>R&amp;D Ratio : incl</li> </ul>	s (in the 3%range for KY0 ugs increased. in decreased. reased 0.2 percenta		
<ul> <li>Drug price revisions</li> <li>Sales of generic dru</li> <li>Sales of Gatifloxaci</li> <li>R&amp;D Ratio : incu</li> <li>¥2.4bln⇒¥2.5blu</li> </ul>	s (in the 3%range for KY0 ugs increased. in decreased. reased 0.2 percenta n +¥1bln	ORIN Pharmaceutical). age points (9.1%⇒9.3	3%)
<ul> <li>Drug price revisions</li> <li>Sales of generic dru</li> <li>Sales of Gatifloxaci</li> <li>R&amp;D Ratio : incu</li> <li>¥2.4bln⇒¥2.5bla</li> <li>SG&amp;A Ratio (ex</li> <li>¥9.8bln⇒¥9.5bla</li> </ul>	s (in the 3%range for KY0 ugs increased. in decreased. reased 0.2 percenta n +¥1bln cluding R&D exper	DRIN Pharmaceutical). Ige points (9.1%⇒9.3 Ises) : decreased 1.4	3%)

Net Income

¥2.7bln

3

# Actual and Forecast of Main Subsidiary Companies



健康はキョーリンの願いです。

				(Units: ¥ billion)
KYORIN pharmaceutical	First quarter Jun/2013 (results)	First quarter Jun/2014(results)	FY 2013 (results)	FY2014 (forecast)
Sales	23.3	22.7	97.7	98.5
Operating profit	4.1	2.9	15.4	14.3
Net profit	3.0	2.4	10.8	10.4

KYORIN Rimedio	First quarter Jun/2013(results)	First quarter Jun/2014(results)	FY 2013 (results)	FY2014 (forecast)
Sales	2.9	4.1	12.4	13.2
Operating profit	0.2	0.6	1.0	0.7
Net profit	0.1	0.4	0.6	0.5

Dr. Program	First quarter Jun/2013 (results)	First quarter Jun/2014(results)	FY 2013 (results)	FY2014 (forecast)
Sales	0.4	0.3	1.8	1.7
Operating profit	0.1	0.0	0.2	0.0
Net profit	0.1	0.0	0.2	0.0

# Main Product Sales Update



#### (Units: ¥ billion)

		Interir	n term	Full	term			First quarte	r(April 1 t	o June 30)	
	Product name	FY2013 (results)	FY2014 (forecast)	FY2013 (results)	FY2014 (forecast)		FY2013 (results)	FY2014 (results)	YoY change (%)	Progress to Interim term forecast(%)	Progress to Full term forecast(%)
	Kipres (LT receptor antagonist)	17.1	17.3	40.2	40.3		8.7	9.1	+4.5%	52.1%	22.5%
	Mucodyne (Mucoregulant)	8.2	7.2	18.4	16.0		4.5	3.4	-25.3%	46.7%	21.0%
Sales of new ethical	Pentasa (Ulcerative colitis and Crohn's disease treatment)	9.4	8.9	18.6	17.5	-	4.7	4.3	-7.5%	48.0%	24.6%
drugs (Japan)	Uritos(Kyorin) (Overactive bladder)	3.7	3.7	8.1	8.2		1.9	1.6	-17.8%	42.1%	19.4%
	Ketas (For bronchial asthma and cerebrovasculas disorders)	1.5	1.2	2.8	2.5		0.8	0.6	-27.6%	42.8%	21.9%
	<b>Flutiform</b> (Anti-asthmatic)		0.8	0.6	2.8		_	0.4	_	55.5%	15.3%
						I I					
Sales of new ethical drugs (over seas)	Gatifloxacin (Bulk • Royalty)	1.0	0.1	1.5	0.5		0.5	0.1	-75.6%	80.9%	22.5%
Over-the- counter drugs	Milton (Disinfectant)	1.0	1.0	2.1	2.0		0.5	0.4	-4.9%	44.3%	21.9%

# Main R&D Activities -1 (July 29, 2014 Release)



#### Ph III ~ Application submitted

\*Changes from the previous announcement (May 9 2014)

	Stage	Compound/	Therapy	Origin	Features	Comments
Japan	Overseas	Code	area/Action	Ongin	i ealures	Comments
Application submitted (3/2014)	(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 (8/2013)	(Europe) Almirall : Application submitted (10/2013) (US) Forest Laboratories : PhII	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 Clinical trial to be prepared	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)

X Discontinued development of KIPRES (Chewable, Oral Granules's additional indication for pediatric patient ) deleted it from the list of R&D activities.

### Main R&D Activities -2 (July 29, 2014 Release)



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

\*Changes from the previous announcement (May 9 2014)

	Stage	Compound/	Theremy area (A stice	Orisia	Factures	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)	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 II (9/2013)		KRP-AM1977X (Oral agent)	New quinolone synthetic antibacterial agent	In-house	<ul> <li>①Superior ability to combat drug-resistant gram- positive bacteria (incl. MRSA)</li> <li>②Outstanding ADME (oral absorption, tissue</li> </ul>		
※Ph II (6/2014)		KRP-AM1977Y (Injection)	New quinolone synthetic antibacterial agent	In-house	migration) ③High degree of safety expected since safety hurdles cleared prior to clinical trials		
Ph I (10/2013)		KRP-EPA605	Overactive bladder	In-house	KRP-EPA605 is a novel selective prostaglandin EP1 receptor, and expected to improve urinary frequency by suppressing detrusor overactivity of the bladder	•Co-development with KISSEI PHARMACEUTICAL CO., LTD.	

x planning to develop gene-therapy product 「Ad-SGE-REIC」 for the treatment of Malignant Pleural Mesothelioma



# Reference



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

(Units:¥ billion)	Sales	Year on Year	Profit	Year on Year
total	26.4	+0.2	3.6	-0.9
Ethical drugs business	26.1	+0.3	3.5	-0.8
Sales of new ethical drugs	21.2	-1.0		
●Japan	21.0	-0.6		
●Overseas	0.2	-0.4		
♦Generic drugs	4.0	+1.3		
♦Over-the-counter drugs	0.9	0.0		
Healthcare(Skincare) business	0.3	-0.1	0.0	-0.1
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, 2015



	Interir	n term	Full	term			First	quarter (A	pril 1 to Jun	e 30)	
(Units: ¥million)	FY2013 (results)	FY2014 (forecast)	FY2013 (results)	FY2014 (forecast)		FY2013 (results)	FY2014 (results)	Change	YoY change (%)	Progress to interim term forecast (%)	Progress to full term forecast (%)
Sales	50,851	51,300	111,400	112,200		26,239	26,397	+157	+0.6%	51.5%	23.5%
Ethical drugs business	50,040	50,600	109,678	110,500		25,801	26,093	+292	+1.1%	51.6%	23.6%
Sales of new ethical drugs	42,858	42,100	93,518	93,100		22,215	21,206	-1,008	-4.5%	50.4%	22.8%
●Japan	41,697	41,700	91,668	92,100		21,582	20,981	-600	-2.8%	50.3%	22.8%
●Overseas	1,160	400	1,849	1,000		633	224	-408	-64.5%	56.2%	22.5%
♦Generic drugs	5,184	6,400	11,987	12,700		2,686	3,973	+1,286	+47.9%	62.1%	31.3%
♦OTC drugs and others	1,997	2,100	4,172	4,600		899	913	+14	+1.6%	43.5%	19.9%
Consumer healthcare business	810	700	1,721	1,700	ļ	438	303	-134	-30.8%	43.3%	17.8%
Operating income	6,213	5,500	17,607	15,800		4,465	3,575	-889	-19.9%	65.0%	22.6%
Ordinary income	6,531	5,700	18,281	16,300		4,681	3,847	-834	-17.8%	67.5%	23.6%
Net income	4,397	3,900	12,025	11,300		2,996	2,681	-315	-10.5%	68.7%	23.7%