# Third Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2013

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## February 4, 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 Third Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2013



(¥ million)	Dec/2009	Dec/2010	Dec/2011	Dec/2012	YoY change (%)	Mar/2013 (forecast)	YoY change (%)
Net Sales	74,579	75,821	77,413	79,229	+2.3%	107,800	) +4.4%
Operating Income	11,045	11,312	11,668	13,711	+17.5%	17,400	) +20.3%
Ordinary Income	11,860	11,848	12,358	14,288	+15.6%	18,000	) +17.8%
Net Income	7,537	7,535	7,227	9,262	+28.2%	11,800	) +27.8%

Third Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2013

【Net sales】 Sales of Kipres and Uritos, and Generic drugs increased year on year, under the influence of the revision of drug prices in April this 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 2.3% year on year, to ¥79.2bln.

[Net income] Gross Profit decreased year on year due to the increase of Cost of Sales Ratio. Meanwhile, SG&A Expenses fell, given a decrease in R&D Expenses. Consequently, Operating Income climbed 17.5% year on year, to ¥13.7 bln,and Net Income rose 28.2% year on year to ¥9.3bln.

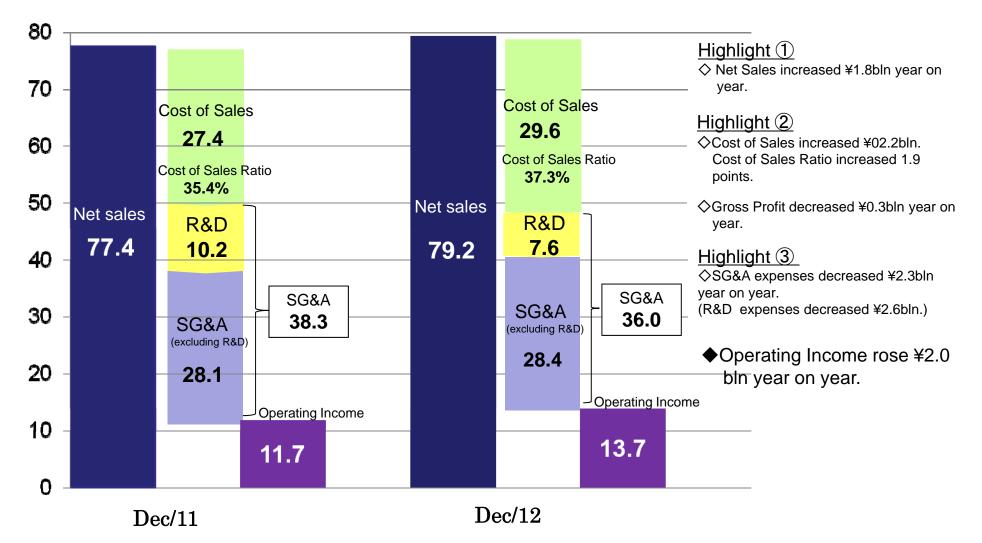
Consolidated Financial Results for the Fiscal Year Ending March 31, 2013(forecast)

[Net sales, Net income] We will not revise the full-year (consolidated) results forecast of Net sales and Net income announced on November 7, 2012 at this moment . (degree of progress: Net sales: 73.5%, operating income: 78.8%)

## **Highlights of Business Performance**



(Units: ¥ billion)



# **Consolidated Financial Results**

### for the Third Quarter ending March 31, 2013



Year on Year

(¥ billion)	Dec/2011	Dec/2012	change
Net Sales (total)	77.4	79.2	+1.8
Ethical drugs Business	75.5	77.8	+2.3
Sales of new ethical drugs	66.0	66.8	+0.8
<ul><li>Japan</li></ul>	64.6	65.1	+0.5
● Overseas	1.4	1.7	+0.3
♦Generic drugs	6.5	7.7	+1.2
Over-the- counter drugs	3.0	3.4	+0.4
Healthcare (Skin care) Business	1.9	1.4	-0.5
Operating Income	11.7	13.7	+2.0
Ordinary Income	12.4	14.3	+1.9
Net Income	7.2	9.3	+2.1

■Net Sales	¥79.2bln	(+ 1.8)
Ethical drugs business	¥77.8bln	(+ 2.3)
● Sales of new ethical drug <u>Dec/2011⇒Dec/20</u>		(+ 0.5)
· Kipres $27.6 \Rightarrow 28.4$ · Mucodyne $16.0 \Rightarrow 14.6$ · Pentasa $14.2 \Rightarrow 13.8$ · Uritos $4.8 \Rightarrow 5.7$	(- 1.4) (- 0.4)	
•	es commenced operations on Oct 1	
<ul> <li>Sales of new ethical drugs in Ov</li> <li>Gatifloxacin 1.2 ⇒ 1.4</li> </ul>		(+ 0.3)
Sales of Generic drugs	(+ 0.2) <b>¥7.7bln</b> Ket's sales and contract manufactur	(+ 1.2) ing's sales increased
Sales of Over-the-counter drug		<b>(+ 0.4)</b>
Healthcare (Skin care) Busine	ess ¥1.4bln	( - 0.5)
Sales declined at Dr. Program		( - 0.5)
<ul> <li>Operating Income</li> <li>Operating Income margin r</li> </ul>	¥13.7bln rose 2.2 percentage points	(+ 2.0) <u>to 17.3%</u>
<ul> <li>Drug price revisions in the</li> <li>Sales of generic drugs increased</li> </ul>	k ⇒37.3% up 1.9 percentage points of the second se	tical
<ul> <li>R&amp;D expenses : up ¥2.6bli</li> <li>R&amp;D Ratio : 13.2%⇒9.5%</li> <li>Expenses associated with the (PENTASA Ph3 、KRP-104Ph</li> </ul>	down 3.7 percentage points progress of the R&D were posted in t	he previous year
●SG&A (excluding R&D exp	oenses) : up ¥0.3bln (¥28.1blr	ı⇒¥28.4bln)
■Net Income	¥9.3bln	(+ 2.1)

# Actual and Forecast of Main Subsidiary Companies Kyorin

KYORIN pharmaceutical	Dec/2011	Dec/2012
Sales	70.3	71.3
Operating Income	11.2	13.2
Net Income	7.2	9.2

	(unit : ¥billion)
Mar/2012	Mar/2013 (forecast)
93.7	96.4
14.0	17.1
9.3	11.8

KYORIN Rimedio	Dec/2011	Dec/2012
Sales	7.1	7.8
Operating Income	0.3	0.1
Net Income	0.3	0.1

Mar/2012 (forecast)	Mar/2011
10.5	10.3
0.6	0.8
0.5	0.6

Dr. Program	Dec/2011	Dec/2012
Sales	1.9	1.4
Operating Income	0.0	-0.2
Net Income	0.0	-0.2

Mar/2012 (forecast)	Mar/2011
2.8	2.8
0.1	0.1
0.1	0.1

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(Units: ¥ billion)

		Interin	n term		Third c	quarter		Full	term
		FY11	FY12	FY11	FY12	Change	Progress to full term forecast(%)	FY11	FY12 (forecast)
	Kipres (LT receptor antagonist)	15.7	16.3	27.6	28.4	+2.7%	74.5%	36.8	38.0
Sales of new	<b>Mucodyne</b> (Mucoregulant)	9.1	8.3	16.0	14.6	-9.3%	72.2%	21.5	20.1
ethical drugs (Japan)	<b>Pentasa</b> (Ulcerative colitis and Crohn's disease treatment)	9.1	9.0	14.2	13.8	-2.8%	77.0%	18.0	17.9
	Uritos (Kyorin) (Overactive bladder)	2.9	3.6	4.8	5.7	+20.6%	72.9%	6.3	7.9
	Ketas (For bronchial asthma and cerebrovasculas disorders)	1.8	1.5	2.7	2.3	-14.9%	76.4%	3.4	3.0
Sales of new ethical drugs (over seas)	<b>Gatifloxacin</b> (Bulk • Royalty)	0.8	0.9	1.2	1.4	+17.3%	83.3%	1.7	1.7
Consumer Healthcare business	<b>Milton</b> (Disinfectant)	0.9	1.0	1.5	1.6	+9.4%	78.4%	1.9	2.0



#### Ph III ~ Application submitted

No Changes from the previous announcement (Nov 7, 2012)

	Stage	Compound/	Therapy	Origin	Features	Comments	
Japan	Overseas	Code area/Action		Chgin		Comments	
XApplication submitted (8/2012)		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 • PhⅢcompleted(2/2012)	
%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>PhⅢcompleted(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)	



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

No Changes from the previous announcement (Nov 7, 2012)

	Stage	Compound/	The result eres (A stice	Origin	Factures	Commonto
Japan	Overseas	Code	Therapy area/Action	Origin	Features	Comments
Ph II (5/2012)	(Europe & US) Almirall: Ph Ⅲ (US) Forest Laboratories : 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.	
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 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 (8/2011)		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 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	



# Reference



## Sales, Profit or Loss of each report segment

(Units:¥ billion)	Sales	Year on Year	Profit	Year on Year
Net Sales (total)	79.2	+1.8	13.7	+2.0
Ethical drugs business	77.8	+2.3	13.8	+2.3
Sales of new ethical drugs	66.8	+0.8		
●Japan	65.1	+0.5		
●Overseas	1.7	+0.3		
♦Generic drugs	7.7	+1.2		
Over-the-counter drugs	3.4	+0.4		
Healthcare(Skincare) business	1.4	-0.5	-0.2	-0.2
Amount of adjustment	_	—	0.1	-0.1

(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 Third Quarter ending March 31, 2013



(Units: ¥ million)	Interim term		Third quarter				Full term		
	FY11	FY12	FY11	FY12	YoY change	YoY Change(%)	Progress to full term forecast(%)	FY11	FY12 (forecast)
Sales	46,387	47,954	77,413	79,229	+1,815	+2.3%	73.5%	103,232	107,800
Ethical drugs business	45,155	47,034	75,495	77,845	+2,350	+3.1%	73.6%	100,654	105,700
♦Sales of new ethical drugs	39,098	39,684	65,996	66,755	+758	+1.1%	73.3%	88,011	91,100
●Japan	38,129	38,661	64,562	65,063	+501	+0.8%	73.4%	85,995	88,600
●Overseas	968	1,023	1,434	1,691	+257	+18.0%	67.6%	2,015	2,500
♦Generic drugs	4,097	5,056	6,450	7,707	+1,256	+19.5%	75.6%	8,656	10,200
♦OTC drugs and others	1,959	2,292	3,047	3,382	+335	+11.0%	76.9%	3,987	4,400
Consumer healthcare business	1,232	920	1,918	1,383	-534	-27.9%	65.9%	2,577	2,100
Operating income	4,900	6,269	11,668	13,711	+2,043	+17.5%	78.8%	14,464	17,400
Ordinary income	5,253	6,609	12,358	14,288	+1,930	+15.6%	79.4%	15,275	18,000
Net income	3,355	4,295	7,227	9,262	+2,035	+28.2%	78.5%	9,231	11,800