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

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## February 2, 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 Third Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2015



(¥ million)	Dec/2011	Dec/2012	Dec/2013	Dec/2014	YoY change (%)	Mar/2015 (forecast)	YoY change (%)
Net Sales	77,413	79,229	83,430	83,602	+0.2%	111,700	+0.3%
Operating Income	11,668	13,711	13,503	10,691	-20.8%	13,800	-21.6%
Ordinary Income	12,358	14,288	13,961	11,181	-19.9%	14,300	-21.8%
Net Income	7,227	9,262	9,272	9,571	+3.2%	11,600	-3.5%

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

[Net sales] Overall net sales increased 0.2% year on year to ¥83.6 billion. Sales growth was driven by year on year increased in a new product Flutiform (prescription limitation was lifted in Dec/2014) and generic drug sales, despite lower sales in the ethical drug due to drug price revision.

[Net income] Gross profit declined ¥2.8 billion year on year due to a rise in the cost ratio, mainly reflecting the revision in the National Health Insurance drug pricing and changes in the product sales mix in the Ethical drugs Business. Operating income amounted to ¥10.6 billion (a decrease of 20.8% year on year) due to a fall in selling, general, and administrative expenses (including R&D expenses). Net income increased at ¥9.5 billion (up 3.2% year on year) due to posting extraordinary income ¥4.5 billion and extraordinary loss ¥1.7 billion.

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

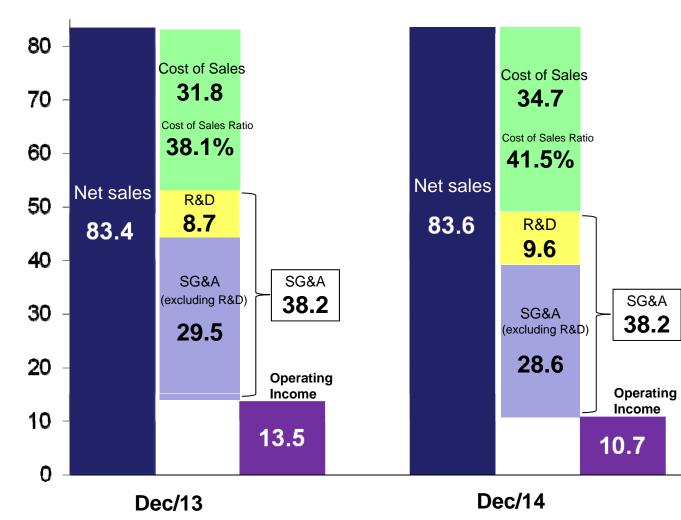
[Net sales, Net income] We will not revise the full-year (consolidated) results forecast of Net sales and Net income announced on November 4, 2014 at this moment .

(degree of progress: Net sales: 74.8%, operating income: 77.5%)

# **Highlights of Business Performance**



(Units: ¥ billion)



>Net Sales increased ¥0.2billion year on year.

decrease of new ethical drugs sales.
increase of generic drugs sales.

Cost of Sales increased ¥2.9 billion.(Cost of sales ratio increased 3.4%)

Drug price revisions

·Sales of generic drugs increased

·Sales of ethical drug overseas decreased

Gross Profit decreased ¥2.8billion year on year

#### >SG&A expenses remained same level.

• R&D expenses increased ¥0.9billion (up front payment)

•SG&A(excluding R&D) decreased ¥0.9billion

■Operating Income decreased ¥2.8billion year on year.

# **Consolidated Financial Results**

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

	Dec/2013	Dec/2014	change
Net Sales (total)	83.4	83.6	+0.2
Ethical drugs Business	82.2	82.6	+0.4
Sales of new ethical drugs	70.3	67.6	-2.7
●Japan	68.8	67.0	-1.8
●Overseas	1.4	0.6	-0.8
♦Generic drugs	8.8	11.9	+3.1
♦Over-the- counter drugs	3.1	3.2	+0.1
Healthcare (Skin care) Business	1.2	1.0	-0.2
Operating Income	13.5	10.7	-2.8
Ordinary Income	14.0	11.2	-2.8

9.3

Net Income

9.6

+0.3

(unit:¥billion)

■Net Sales				¥83.6bln	(+ 0.2)
◆Ethical drugs	s busine	SS		¥82.6bln	(+ 0.4)
Sales of ne	ew ethica	l drug	S	¥67.0bln	( - 1.8)
<u>Dec/2013⇒Dec/2014</u>					
<ul> <li>Kipres</li> <li>Mucodyne</li> <li>Pentasa</li> <li>Uritos</li> <li>Flutiform</li> </ul>	$\begin{array}{rcl} 29.6 & \Rightarrow \\ 14.0 & \Rightarrow \\ 14.5 & \Rightarrow \\ 5.9 & \Rightarrow \\ 0.3 & \Rightarrow \end{array}$	29.3 10.6 13.4 5.5 2.6	(-0.3) (-3.4) (-1.1) (-0.4) (+2.3)		
Sales of new e	-	s in Ove	erseas	¥0.6bln	( - 0.8)
<ul> <li>Gatifloxacir</li> </ul>	n 1.2 ⇒	0.3	(-0.9)	<b>\</b>	
			( 0.0		
Sales of Gene	-		( )	¥11.9bln	(+ 3.1)
	ufacturing's s		d Health i		· · ·
Contract man	ufacturing's s - <b>the-counte</b>	er drug	d Health i <b>s</b>	, <b>¥11.9bIn</b> nsurance pharmacy mar	ket's sales increased
•Contract man Sales of Over	ufacturing's s -the-counte kin care) B	er drug	d Health i <b>s</b>	¥11.9bIn nsurance pharmacy mar ¥3.2bIn	ket's sales increased (+ 0.1)
•Contract man Sales of Over •Healthcare (SI <b>Operating In</b>	ufacturing's s -the-counte kin care) B come	er drug: Busine:	d Health i s ss	¥11.9bIn nsurance pharmacy mar ¥3.2bIn ¥1.0bIn	ket's sales increased (+ 0.1) ( - 0.2) ( - 2.8)
•Contract man Sales of Over •Healthcare (Si Depending Ind •Operating Ind	ufacturing's s -the-counte kin care) B come come mai	er drugs Busines rgin de	d Health i s ss ecreas	¥11.9bIn nsurance pharmacy mar ¥3.2bIn ¥1.0bIn ¥10.7bIn	ket's sales increased (+ 0.1) ( - 0.2) ( - 2.8) e points to 12.8%
Contract man     Sales of Over     Healthcare (Si     Operating Inc     Operati	ufacturing's s -the-counter kin care) B come come mai es Ratio : 3 evisions (in t	er drug: Busine: Cgin do 38.1%= he 6%r:	d Health i s ss ecreas ⇒41.5% ange for	¥11.9bIn nsurance pharmacy mar ¥3.2bIn ¥1.0bIn ¥10.7bIn ed 3.4 percentage	ket's sales increased (+ 0.1) ( - 0.2) ( - 2.8) e points to 12.8% rcentage points ical).
Contract man     Sales of Over     Healthcare (Si     Operating In     Operating In     Operating In     Operating In     Operating In     Operating In	tifacturing's s -the-counter kin care) B come come mai es Ratio : 3 evisions (in t eric drugs in	er drug Gusines rgin d 38.1%= he 6%ra acrease	d Health i s ss ecreas ⇒41.5% ange for d. ∙Sale	¥11.9bInnsurance pharmacy mar¥3.2bIn¥1.0bIn¥10.7bIned 3.4 percentageincreased 3.4 perKYORIN Pharmaceut	ket's sales increased (+ 0.1) ( - 0.2) ( - 2.8) e points to 12.8% rcentage points ical). eased.
Contract man     Sales of Over     Healthcare (Si     Operating In     Operating In     Operating In     Operating In     Operating In     Operating In	ufacturing's s -the-counter kin care) B come come mai es Ratio : 3 evisions (in t eric drugs in 10.4%⇒1	er drug: Busine: Cgin do 38.1%= he 6%ra hcrease 1.5%	d Health i s ss ecreas ⇒41.5% ange for d. •Sale increas	¥11.9bInnsurance pharmacy mar¥3.2bIn¥1.0bIn¥10.7bIned 3.4 percentageincreased 3.4 perKYORIN Pharmaceutes of Gatifloxacin decr	ket's sales increased (+ 0.1) ( - 0.2) ( - 2.8) e points to 12.8% rcentage points ical). eased. points
<ul> <li>Contract man</li> <li>Sales of Over</li> <li>Healthcare (Si</li> <li>Operating Ind</li> <li>Operating Ind</li> <li>Cost of Sale</li> <li>Drug price re</li> <li>Sales of gen</li> <li>R&amp;D Ratio : * ¥8.7bln ⇒ ¥8</li> <li>SG&amp;A Ratio * ¥29.5bln ⇒ ¥8</li> </ul>	the-counter the-	er drug: susine: gin de s8.1%= he 6%r; acrease 1.5% 9bln) ≥34.2% ∉0.9bln)	d Health i s ss ecreas ⇒41.5% ange for d. •Sale increas up front o decre	¥11.9bInnsurance pharmacy mar¥3.2bIn¥1.0bIn¥10.7bIned 3.4 percentageincreased 3.4 perKYORIN Pharmaceutes of Gatifloxacin decrsed 0.9 percentage	ket's sales increased (+ 0.1) ( - 0.2) ( - 2.8) e points to 12.8% rcentage points ical). eased. points /

•extraordinary income : 4.5 billion yen for the transfer of the land and building of the former head office building •extraordinary losses : 1.7 billion yen for the use of the vacant lot of the Pharmaceutical Discovery Research Laboratories



# Actual and Forecast of Main Subsidiary Companies Kyorin

(unit : ¥billion)

KYORIN pharmaceutical	Dec/2013	Dec/2014
Sales	73.6	72.6
Operating Income	12.1	8.8
Net Income	8.6	8.4

Mar/2014	Mar/2015 (forecast)
97.7	97.1
15.4	11.5
10.8	10.2

KYORIN Rimedio	Dec/2013	Dec/2014
Sales	9.1	12.2
Operating Income	0.5	1.5
Net Income	0.3	1.0

Mar/2014	Mar/2015 (forecast)
12.4	15.3
1.0	1.6
0.6	1.0

Dr. Program	Dec/2013	Dec/2014
Sales	1.2	1.0
Operating Income	0.1	-0.1
Net Income	0.1	-0.1

Mar/2014	Mar/2015 (forecast)
1.8	1.6
0.2	0.0
0.2	0.0

# Main Product Sales Update



								( Unit	s:¥billion)
Product name		Interin	n term	Third quarter F			Full	Full term	
		Sep/2013	Sep/2014	Dec/2013	Dec/2014	Change	Progress to full term forecast(%)	Mar/2014	Mar/2015 (forecast)
	Kipres (LT receptor antagonist)	17.1	17.4	29.6	29.3	-1.1%	72.9%	40.2	40.2
	<b>Mucodyne</b> (Mucoregulant)	8.2	6.2	14.0	10.6	-24.6%	76.2%	18.4	13.8
Sales of new	Pentasa (Ulcerative colitis and Crohn's disease treatment)	9.4	8.6	14.5	13.4	-7.3%	80.3%	18.6	16.7
ethical drugs (Japan)	Uritos (Kyorin) (Overactive bladder)	3.7	3.4	5.9	5.5	-7.5%	72.6%	8.1	7.5
	Ketas (For bronchial asthma and cerebrovasculas disorders)	1.5	1.1	2.2	1.6	-26.8%	76.5%	2.8	2.1
	Flutiform (Combination drug for asthma treatment)	_	0.9	0.3	2.6	+641.6%	64.2%	0.6	3.9
Sales of new ethical drugs (over seas)	<b>Gatifloxacin</b> (Bulk • Royalty)	1.0	0.1	1.2	0.3	-75.1%	57.4%	1.5	0.5
				1					
Over-the- counter drugs	<b>Milton</b> (Disinfectant)	1.0	1.0	1.6	1.5	-2.4%	76.9%	2.1	1.9

# Main R&D Activities -1 (Feb 2 , 2015 Release)



### Ph III ~ Application submitted

\*Changes from the previous announcement (Nov 4 2014)

Stage		Compound/	Therapy	Origin	Features	Comments	
Japan	Overseas	Code	area/Action	Origin	realures	Comments	
Application submitted (3/2014)	(Europe) AstraZeneca : Launched(9/2012) (US) Actavis : 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) AstraZeneca : Approval (11/2014) (US) Actavis : 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)	

# Main R&D Activities -2 (Feb 2, 2015 Release)



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

\*Changes from the previous announcement (Nov 4 2014)

Stage		Stage Compound/		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	<ol> <li>Superior ability to combat drug-resistant gram- positive bacteria (incl. MRSA)</li> <li>Outstanding ADME (oral absorption, tissue</li> </ol>		
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		

### for reference

Stage	Compound/ Code	Therapy area/Action	Features	Comments
under development by MSD K.K.	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



## Sales, Profit or Loss of each report segment

	Sales	change Y/Y	Profit	change Y/Y
Net Sales (total)	83.6	+0.2	10.7	-2.8
Ethical drugs business	82.6	+0.4	10.6	-2.4
Sales of new ethical drugs	67.6	-2.7		
OJapan	67.0	-1.8		
OOverseas	0.6	-0.8		
♦Generic drugs	11.9	+3.1		
Over-the-counter drugs	3.2	+0.1		
Healthcare(Skincare) business	1.0	-0.2	-0.1	-0.2
Amount of adjustment		_	0.2	-0.2

(Units: ¥ billion)

(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, 2015



(unit : ¥million)	Interim term		Third quarter				Full term		
	Sep/2013	Sep/2014	Dec/2013	Dec/2014	Change	% Y/Y	Progress to full term forecast(%)	Mar/2014	Mar/2015 (forecast)
Sales	50,851	51,112	83,430	83,602	+172	+0.2%	74.8%	111,400	111,700
Ethical drugs business	50,040	50,518	82,223	82,629	+406	+0.5%	75.1%	109,678	110,000
♦Sales of new ethical drugs	42,858	40,755	70,276	67,564	-2,711	-3.9%	74.4%	93,518	90,800
●Japan	41,697	40,422	68,843	66,986	-1,856	-2.7%	74.7%	91,668	89,700
Overseas	1,160	332	1,433	577	-855	-59.7%	57.8%	1,849	1,000
♦Generic drugs	5,184	7,790	8,806	11,873	+3,066	+34.8%	79.2%	11,987	15,000
♦OTC drugs and others	1,997	1,972	3,140	3,191	+51	+1.6%	76.0%	4,172	4,200
Consumer healthcare business	810	593	1,206	972	-234	-19.4%	60.8%	1,721	1,600
Operating income	6,213	4,587	13,503	10,691	-2,812	-20.8%	77.5%	17,607	13,800
Ordinary income	6,531	4,898	13,961	11,181	-2,779	-19.9%	78.2%	18,281	14,300
Net income	4,397	3,495	9,272	9,571	+298	+3.2%	82.5%	12,025	11,600