

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

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**February 3, 2016**

**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, 2016



(¥ million)	Dec/2012	Dec/2013	Dec/2014	Dec/2015	YoY change (%)	Mar/2016 (revised forecast)	YoY change (%)	Mar/2016 (original forecast)	YoY change (%)
Net Sales	79,229	83,430	83,602	89,469	+7.0	120,200	+6.3	120,200	+6.3%
Operating Income	13,711	13,503	10,691	14,666	+37.2	19,400	+31.6	16,000	+8.6%
Ordinary Income	14,288	13,961	11,181	14,946	+33.7	19,700	+27.2	16,300	+5.2%
Net Income	9,262	9,272	9,571	10,831	+13.2	13,000	+7.8	11,500	-4.7%

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

**【Net Sales】** Overall net sales increased 7.0% year on year to ¥89.4bln. Sales growth was driven by year on year increased of main products such as Flutiform and received an upfront payment of a license agreement.

**【Profit】** Gross profit rose 5.4bln yen year on year due to received an upfront payment and slight decrease of the cost ratio. SG & A expenses increased 1.4bln yen year on year, At the other side, operating income increased 37.2% to ¥14.6bln(+3.9bln yen), net income increased 13.2% to 10.8bln year on year.

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

**【Net Sales】** After taking into account the trend in earnings until the cumulative third quarter of the current fiscal year, the Company has revised down its sales forecast for the generic drug business. However, for the new drug business, the Company has revised up its sales forecast because it has recorded an upfront payment revenue resulting from the conclusion of a license agreement. On an overall basis, the Company has retained its original forecast.

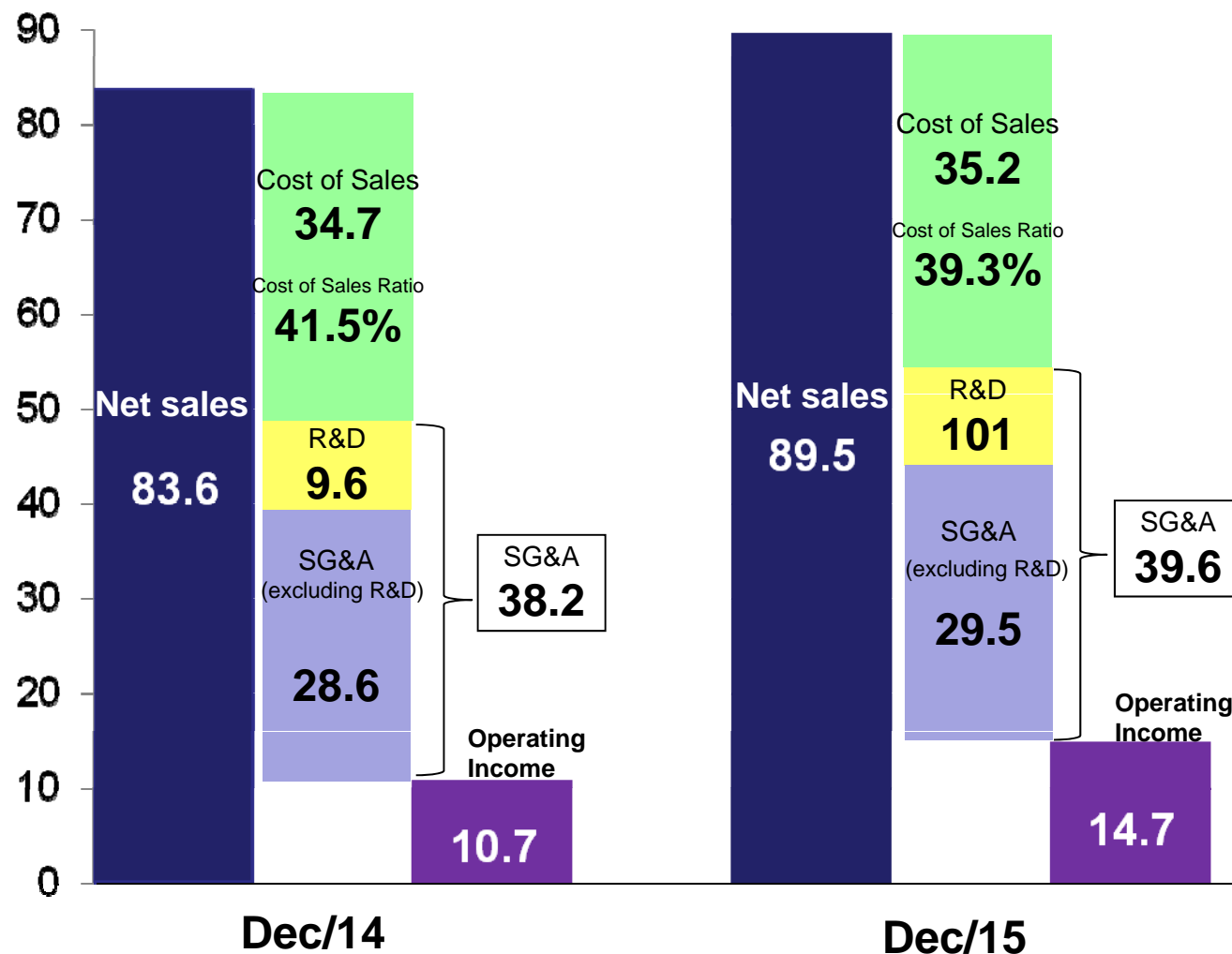
**【Profit】** Owing to the incorporation of upfront payment revenue resulting from the conclusion of a license agreement, the Company has revised up estimated operating income to ¥19.4 billion (an increase of ¥3.4 billion), ordinary income to ¥19.7 billion (an increase of ¥3.4 billion), and net income to ¥13.0 billion (an increase of ¥1.5 billion). Note that, in addition to an extraordinary gain of approximately ¥1.8 billion stemming from the transfer of fixed assets (September 30, 2015 press release), we have factored in the current estimated amount of costs relating to the transfer of the production functions of the Okaya Plant of Kyorin Pharmaceutical Co., Ltd. to KYORIN Pharmaceutical Facilities Co., Ltd., which is under consideration at present.

In regard to dividends, the Company will implement a shareholder return targeting a dividend payout ratio of 30%, in accordance with the basic policy.

◇The full year forecast of consolidated results for the year ending March 31, 2016, released on May 13, 2015, has been revised in this document.

# Highlights of Business Performance

( Units: ¥ billion )



➤ **Net Sales increased ¥5.9billion year on year.**  
 · increase of Flutiform, Kipres sales  
 · an upfront payment of a license agreement

➤ **Cost of sales ratio decreased 2.2%.**  
 · Sales of main product increased  
 · an upfront payment of a license agreement

■ **Gross Profit increased ¥5.4billion year on year .**

➤ **SG&A expenses increased ¥1.4billion year on year.**  
 · R&D expenses increased ¥0.5billion  
 · SG&A(excluding R&D) increased ¥0.9billion

■ **Operating Income increased ¥4.0billion year on year.**

# Consolidated Financial Results

## for the Third Quarter ending March 31, 2016



(unit : ¥ billion)

Year on Year

	Dec/2014	Dec/2015	change
Net Sales (total)	83.6	<b>89.5</b>	+5.9
Ethical drugs Business	82.6	<b>88.6</b>	+6.0
◆Sales of new ethical drugs	67.6	<b>73.7</b>	+6.1
●Japan	67.0	<b>68.6</b>	+1.6
●Overseas	0.6	<b>5.1</b>	+4.5
◆Generic drugs	11.9	<b>11.4</b>	-0.5
◆Over-the-counter drugs	3.2	<b>3.4</b>	+0.2
Healthcare (Skin care) Business	1.0	<b>0.9</b>	-0.1
Operating Income	10.7	<b>14.7</b>	+4.0
Ordinary Income	11.2	<b>14.9</b>	+3.7
Net Income	9.6	<b>10.8</b>	+1.2

■Net Sales	¥89.5bln	(+ 5.9)
◆Ethical drugs business	¥88.6bln	(+ 6.0)
● Sales of new ethical drugs	¥68.6bln	(+ 1.6)
Dec/2014⇒Dec/2015		
· Kipres	29.3 ⇒ 32.0 (+2.7)	
· Flutiform	2.6 ⇒ 5.2 (+2.6)	
· Uritos	5.5 ⇒ 5.7 (+0.2)	
· Mucodyne	10.6 ⇒ 9.9 (-0.7)	
· Pentasa	13.4 ⇒ 12.7 (-0.7)	
● Sales of new ethical drugs in Overseas	¥5.1bln	(+ 4.5)
· Gatifloxacin	0.3 ⇒ 0.5 (+0.2)	
· up front payment of FPR-2 agonists (12/2015)		
● Sales of Generic drugs	¥11.4bln	( - 0.5)
· increase of Health insurance pharmacy market's sales		
· decrease of Contract manufacturing's sales		
● Sales of Over-the-counter drugs	¥3.4bln	(+ 0.2)
◆Healthcare (Skin care) Business	¥0.9bln	( - 0.1)
■Operating Income	¥14.7bln	( + 4.0)
◆Operating Income margin increased 3.6 percentage points to 16.4%		
● Cost of Sales Ratio : 41.5%⇒39.3% decreased 2.2 percentage points		
· Sales of main product increased (Flutiform:30days,120 inhalations)		
· an up front payment of FPR-2 agonists		
● R&D Ratio : 11.5%⇒11.3% decreased 0.2 percentage points		
* ¥9.6bln⇒¥10.1bln (+¥0.5bln) cost of new WATARASE research center , progress of project		
● SG&A Ratio : 34.2%⇒33.0% decreased 1.2 percentage		
* ¥28.6bln⇒¥29.5bln (+¥0.9bln) increase of patent royalty ,sales costs,		
■Net Income	¥10.8bln	(+ 1.2)

# Main Product Sales Update

( Units: ¥ billion )

Product name		Sep/2014	Sep/2015	Dec/2014	Dec/2015	%Change	Progress to full term forecast(%)	Mar/2015	Mar/2016 (revised forecast)	Mar/2016 (original forecast)
Sales of new ethical drugs (Japan)	<b>Kipres</b> (LT receptor antagonist)	17.4	18.8	29.3	<b>32.0</b>	+9.2%	74.4%	41.2	<b>43.0</b>	41.8
	<b>Flutiform</b> (Combination drug for asthma treatment)	0.9	3.0	2.6	<b>5.2</b>	+105.6%	69.9%	3.6	<b>7.5</b>	10.3
	<b>Uritos (Kyorin)</b> (Overactive bladder)	3.4	3.7	5.5	<b>5.7</b>	+5.0%	75.6%	7.3	<b>7.6</b>	7.9
	<b>Mucodyne</b> (Mucoregulant)	6.2	5.9	10.6	<b>9.9</b>	-6.0%	78.1%	14.0	<b>12.7</b>	11.8
	<b>Pentasa</b> (Ulcerative colitis and Crohn's disease treatment)	8.6	8.1	13.4	<b>12.7</b>	-5.5%	77.4%	17.2	<b>16.4</b>	17.1
Over-the-counter drugs	<b>Milton</b> (Disinfectant)	1.0	1.0	1.5	<b>1.6</b>	+5.8%	80.6%	2.0	<b>2.0</b>	2.0

# Main R&D Activities -1 (Feb 3 , 2016 Release)

## Ph III ~ Application submitted

※Changes from the previous announcement(Nov 6 2015)

Stage		Compound/ Code	Therapy area/Action	Origin	Features	Comments
Japan	Overseas					
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	①Superior ability to combat drug-resistant gram-positive bacteria (incl. MRSA) ②Outstanding ADME (oral absorption, tissue migration) ③High degree of safety expected since safety hurdles cleared prior to clinical trials	

※A license agreement for KRP-AB1102F with AstraZeneca was terminated and Kyorin reached the conclusion that the rights should be returned to AstraZeneca. For details, please refer to the Press Release announced today(February 3).

## for reference

Stage	Compound/ Code	Therapy area/Action	Features	Comments
Application submitted 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)

# Main R&D Activities -2 (Feb 3 , 2016 Release)

## POC Project (Ph I ~ Ph II)

※Changes from the previous announcement(Nov 6 2015)

Stage		Compound/ Code	Therapy area/Action	Origin	Features	Comments
Japan	Overseas					
Ph II (8/2015)	Ph III 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 (6/2014)		KRP-AM1977Y (Injection)	New quinolone synthetic antibacterial agent	In-house	①Superior ability to combat drug-resistant gram-positive bacteria (incl. MRSA) ②Outstanding ADME (oral absorption, tissue migration) ③High degree of safety expected since safety hurdles cleared prior to clinical trials	
Ph I , II (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 gene-therapy 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)

# Main R&D Activities -3 (Feb 3 , 2016 Release)

## Licensing development (preclinical)

※Changes from the previous announcement(Nov 6 2015)

Stage/ Overseas	Compound/ Code	Licensee / Collaborative research	Therapy area/Action	Origin	Features	Comments
Ph I	KRP-203	Novartis	GVHD	In-house	Sphingosine-1-Phosphate Receptor Agonist . immunomodulatory drug.	License agreement with Novartis (2/2006)  Novartis has decided to proceed with development of KRP-203 for GvHD.
※Preclinical	-	BMS	Non- disclosure	In-house	FPR-2 agonists that mainly inhibit the migration of neutrophils and exhibit anti- inflammatory action.	License agreement with BMS (12/2015)



# Reference

# Segment information for the Third Quarter Ending March 31, 2016

## Sales, Profit or Loss of each report segment

( Units: ¥ billion )

	Sales	change Y/Y	Profit	change Y/Y
<b>Net Sales (total)</b>	89.5	+5.9	14.7	+4.0
<b>Ethical drugs business</b>	88.6	+6.0	14.5	+3.9
◆Sales of new ethical drugs	73.7	+6.1		
○Japan	68.6	+1.6		
○Overseas	5.1	+4.5		
◆Generic drugs	11.4	-0.5		
◆Over-the-counter drugs	3.4	+0.2		
<b>Healthcare(Skincare) business</b>	0.9	-0.1	0	+0.1
<b>Amount of adjustment</b>	—	—	0.2	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 Third Quarter ending March 31, 2016



(unit : ¥million)	Interim term		Third quarter					Full term		
	Sep/2014	Sep/2015	Dec/2014	Dec/2015	Change	% Y/Y	Progress to full term forecast(%)	Mar/2015	Mar/2016 (revised forecast)	Mar/2016 (original forecast)
<b>Sales</b>	51,112	52,386	83,602	<b>89,469</b>	+5,867	+7.0%	74.4%	113,121	<b>120,200</b>	120,200
<b>Ethical drugs business</b>	50,518	51,783	82,629	<b>88,559</b>	+5,930	+7.2%	74.7%	111,771	<b>118,500</b>	118,600
◆Sales of new ethical drugs	40,755	42,229	67,564	<b>73,713</b>	+6,149	+9.1%	75.4%	92,111	<b>97,800</b>	95,700
●Japan	40,422	41,634	66,986	<b>68,615</b>	+1,629	+2.4%	74.2%	91,079	<b>92,500</b>	94,700
●Overseas	332	594	577	<b>5,098</b>	+4,521	+785.5%	98.0%	1,032	<b>5,200</b>	1,000
◆Generic drugs	7,790	7,393	11,873	<b>11,435</b>	-438	-3.7%	71.0%	15,477	<b>16,100</b>	18,200
◆OTC drugs and others	1,972	2,160	3,191	<b>3,410</b>	+219	+6.9%	74.1%	4,183	<b>4,600</b>	4,500
<b>Consumer healthcare business</b>	593	603	972	<b>910</b>	-62	-6.4%	56.9%	1,349	<b>1,600</b>	1,600
<b>Operating Income</b>	4,587	4,099	10,691	<b>14,666</b>	+3,975	+37.2%	75.6%	14,737	<b>19,400</b>	16,000
<b>Ordinary Income</b>	4,898	4,266	11,181	<b>14,946</b>	+3,765	+33.7%	75.9%	15,490	<b>19,700</b>	16,300
<b>Net Income</b>	3,495	2,967	9,571	<b>10,831</b>	+1,260	+13.2%	83.3%	12,064	<b>13,000</b>	11,500