

Third Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2017

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February 3, 2017

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, 2017

(¥ million)	Dec/2013	Dec/2014	Dec/2015	Dec/2016	YoY change (%)	Mar/2017 (revised forecast)	YoY change (%)	Mar/2017 (original forecast)	YoY change (%)
Net Sales	83,430	83,602	89,469	86,836	-2.9	115,000	-3.8	120,000	+0.4%
Operating Income	13,503	10,691	14,666	7,313	-50.1	10,000	-49.1	14,500	-26.2%
Ordinary Income	13,961	11,181	14,946	7,716	-48.4	10,400	-48.0	14,900	-25.5%
Net Income	9,272	9,571	10,831	4,723	-56.4	6,600	-51.6	10,700	-21.6%

Third Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2017

【Net Sales】 Sales of new pharmaceutical products in Japan decreased due to decline in prescriptions of long-listed items and the drug price revisions. On the other hand, sales of generic drugs increased due to the launch of an authorized generic (AG) of Montelukast (KIPRES), and sales in the ethical pharmaceuticals category in Japan were higher than last year. However, new pharmaceutical products overseas declined in the absence of upfront payment income recorded in the previous year. Accordingly, total net sales fell to 86,836 million yen (2.9% year-on-year decrease).

【Profit】 Gross profit on sales decreased by 5,737 million yen due to a rise in the cost rate, reflecting drug price revisions and an increase in the sales weight of generic drugs, as well as a decline in upfront payment income in new pharmaceutical products overseas. SG&A expenses increased by 1,614 million yen (including a 705 million yen increase in R&D expenses), and operating income decreased to 7,313 million yen (a 50.1% year-on-year decrease). Net income attributable to owners of parent came to 4,723 million (down 56.4% from a year earlier) because expenses of around 1,000 million yen related to the settlement of a lawsuit for violation of US antitrust laws in connection with an in-licensed product (*Gatifloxacin eyedrops*) were recorded as an extraordinary loss.

Consolidated Financial Results for the Fiscal Year Ending March 31, 2017 (forecast)

The consolidated financial results forecast for the fiscal year ending March 31, 2017 announced in the news release of May 12 2016 *Summary of Consolidated Financial Results (For the fiscal year ended March, 2016)* was revised as follows.

【Net Sales】 It is now expected that, in new pharmaceutical products in Japan, sales of core products will be less than initially forecast and, in new pharmaceutical products overseas, upfront payment income relating to an in-licensed product will be postponed to a subsequent term. Meanwhile, in generic drugs, sales of the AG version of Montelukast (KIPRES) are expected to exceed the initial forecast. Accordingly, the initial forecast for overall net sales was lowered.

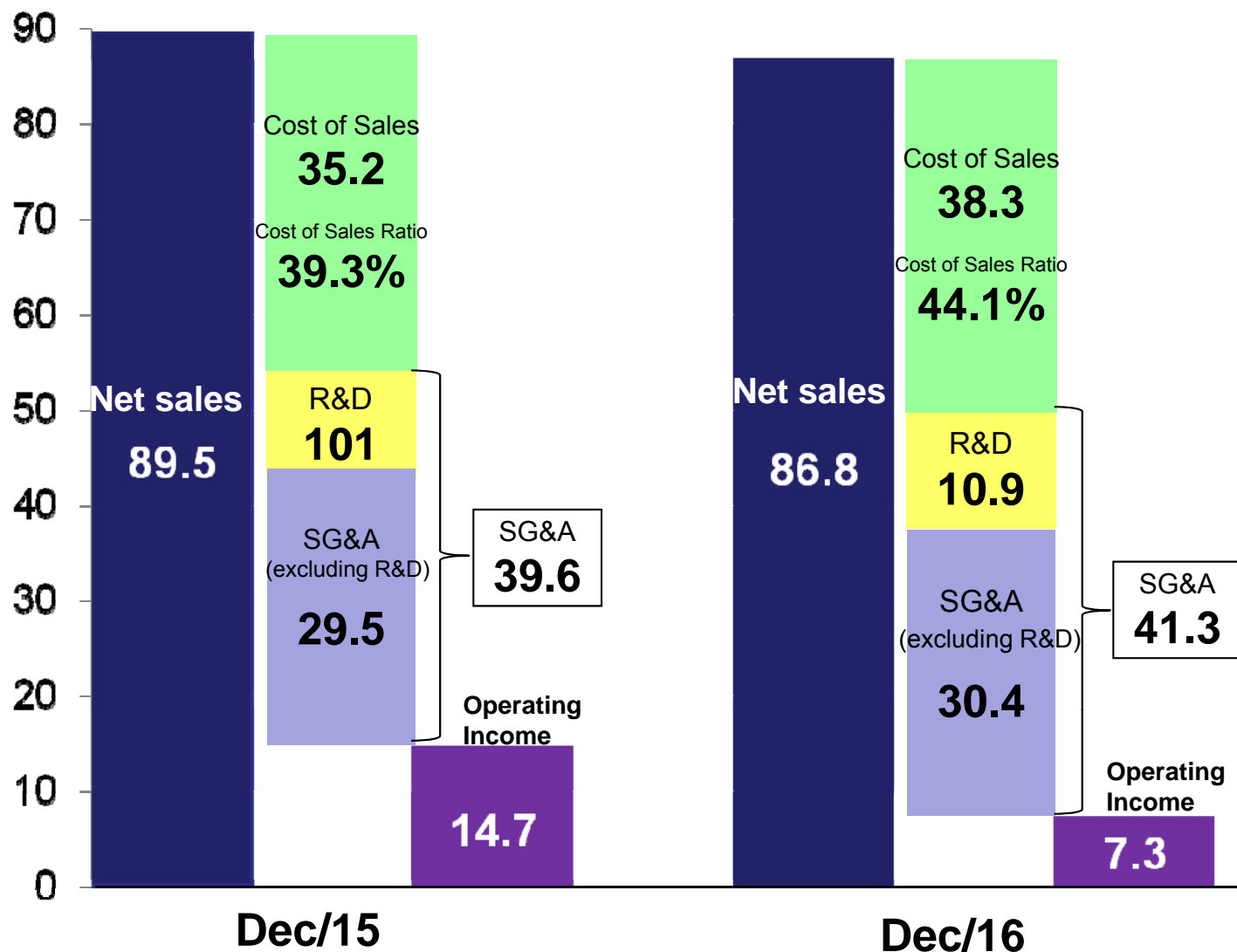
【Profit】 The forecasts for operating income, ordinary income and net income attributable to owners of parent were lowered, mainly because net sales are now expected to be lower than initially forecast. As explained above, an extraordinary loss of around 1,000 million yen was recorded in the third quarter.

【Dividends】

There is no change to the dividend forecast (annual dividend of 58 per share) announced on May 12, 2016.

Highlights of Business Performance

(Units: ¥ billion)



➤ Net Sales decreased ¥2.7billion year on year.
 • Decrease of new ethical drugs sales (Japan and overseas)
 • Increase of generic drugs sales

➤ Cost of sales ratio increased 4.8%.
 • Drug price revisions
 • Sales of ratio generic drugs increased
 • Decrease of upfront payment income for in-licensed product overseas

■ Gross Profit decreased ¥5.7billion year on year .

➤ SG&A expenses increased ¥1.7billion year on year.

• R&D expenses increased ¥0.8billion
 • SG&A(excluding R&D) increased ¥0.9billion

■ Operating Income decreased ¥7.4billion year on year.

Consolidated Financial Results

for the Third Quarter ending March 31, 2017

(unit : ¥ billion)

Year on Year

	Dec/2015	Dec/2016	Change
Net Sales (total)	89.5	86.8	-2.7
Ethical drugs Business	85.3	82.5	-2.8
◆ Sales of new ethical drugs	73.9	64.4	-9.5
● Japan	68.8	64.1	-4.7
● Overseas	5.1	0.3	-4.8
◆ Generic drugs	11.4	18.1	6.7
Healthcare Business	4.2	4.3	0.1
Operating Income	14.7	7.3	-7.4
Ordinary Income	14.9	7.7	-7.2
Net Income	10.8	4.7	-6.1

(Note) The details of the Sales Segment have been changed from the first quarter ending March 31, 2017. Following the change, the Pharmaceutical Business comprises New Drugs and Generic Drugs, while the Health Care Business comprises Skincare, Environmental Hygiene and Over the Counter Drugs and Others.

■ Net Sales **¥86.8bln** (− 2.7)

◆ Ethical drugs business **¥82.5bln** (− 2.8)

● Sales of new ethical drugs **¥64.1bln** (− 4.7)

Dec/2015⇒Dec/2016

· Kipres※	32.0	⇒	26.0	(−6.0)
· Flutiform	5.2	⇒	7.6	(+2.4)
· Uritos	5.7	⇒	5.8	(+0.1)
· Pentasa	12.7	⇒	12.0	(−0.7)
· Mucodyne	9.9	⇒	7.5	(−2.4)

※ Launch of an authorized generic drug (AG) for KIPRES

● Sales of new ethical drugs in Overseas **¥0.3bln** (− 4.8)

· Decrease of upfront payment income for FPR-2 agonists (12/2015)

● Sales of Generic drugs **¥18.1bln** (+ 6.7)

· Sales of the MONTELUKAST"AG" for KIPRES and the other generic drugs increased

◆ Healthcare Business **¥4.3bln** (+ 0.1)

■ Operating Income **¥7.3bln** (− 7.4)

◆ Operating Income margin decreased 8.0 percentage points to 8.4%

● Cost of Sales Ratio : 39.3%⇒44.1% increased 4.8 percentage points

· Drug price revisions
· Sales of generic drugs increased · Decrease of upfront payment income for in-licensed product overseas

● R&D Ratio : 11.3%⇒12.5% increased 1.2 percentage points

* ¥10.1bln⇒¥10.9bln (+¥0.8bln) progress of project(KRP-AM1977X, KRP-114V)

● SG&A Ratio : 33.0%⇒35.0% increased 2.0 percentage

* ¥29.5bln⇒¥30.4bln (+¥0.9bln) · increase of Labor costs

■ Net Income **¥4.7bln** (− 6.1)

* Expenses of around 1,000 million yen relating to the settlement of a lawsuit for violation of U.S. antitrust laws in connection with an in-licensed product (Gatifloxacin eyedrops) were recorded as an extraordinary loss.

Main Product Sales Update

(Units: ¥ billion)

Product name		Sep/2015	Sep/2016	Dec/2015	Dec/2016	%Change	Mar/2016	Mar/2017 (revised forecast)	Mar/2017 (original forecast)
new ethical drugs (Japan)	Kipres (LT receptor antagonist)	18.8	17.8	32.0	26.0	-18.8%	44.1	31.9	33.3
	Flutiform (Combination drug for asthma treatment)	3.0	4.5	5.2	7.6	+44.1%	7.2	10.1	12.9
	Uritos (Kyorin) (Overactive bladder)	3.7	3.8	5.7	5.8	+0.5%	7.5	7.6	7.8
	Desalex (Antiallergic Agent)	—	—	—	0.7	—	—	1.9	1.9
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	8.1	7.9	12.7	12.0	-5.2%	16.1	15.5	15.8
	Mucodyne (Mucoregulant)	5.9	4.4	9.9	7.5	-24.4%	13.0	9.7	10.8
Generic drugs	MONTELUKAST Tablets "KM"※	—	1.8	—	5.3	—	—	7.1	4.1

※Authorized generic drug for KIPRES

Revision of Earnings Forecasts

(unit : ¥million)

	Mar/2016	Mar/2017 (original forecast)	Mar/2017 (revised forecast)	Versus the original forecast
Sales	119,483	120,000	115,000	−5,000
Ethical drugs business	113,970	114,000	109,100	−4,900
◆Sales of new ethical drugs	98,506	92,400	84,900	−7,500
●Japan	92,920	88,500	84,000	−4,500
●Overseas	5,586	3,800	800	−3,000
◆Generic drugs	15,465	21,500	24,100	+2,600
healthcare business	5,512	6,000	5,900	−100

【Main factors behind revision of net sales forecast】

➤ New pharmaceutical products

Japan: Initial forecast was revised to reflect lower than anticipated sales of core products

Overseas: Initial forecast was revised to reflect the postponement of upfront payment income relating to an in-licensed product to a subsequent term

➤ **Generic drugs:** The forecast was revised to reflect sales of the AG version of Montelukast (KIPRES)

【Main factors behind the revision of forecasts for operating income, ordinary income and net income attributable to owners of parent】

➤ The initial forecasts were revised mainly because net sales were less than forecast.

➤ Expenses of around 1,000 million yen relating to the settlement of a lawsuit for violation of U.S. antitrust laws in connection with an in-licensed product (*Gatifloxacin eyedrops*) were recorded as an extraordinary loss in the third quarter.

Main R&D Activities -1 (Feb 3 , 2017 Release)

Ph III ~ Application submitted

※Changes from the previous announcement(Nov 7 2016)

Stage		Compound/ Code	Therapy area/Action	Origin	Features	Comments
Japan	Overseas					
Ph III (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) Co-Development and Co- Marketing Agreement with Kissei Pharmaceutical Co., Ltd. affiliate . (3/2016)
※Preparing for Application		KRP-AM1977X (Oral agent)	New quinolone synthetic antibacterial agent	In-house	-Superior ability to combat drug-resistant gram- positive bacteria (incl. MRSA) -has a powerful antimicrobial activity against anaerobic bacteria	
Ph III (3/2016)		KRP-AM1977Y (Injection)	New quinolone synthetic antibacterial agent	In-house	- Expectation of high clinical effects with excellent tissue penetration -High degree of safety expected since safety hurdles cleared prior to clinical trials	

※Release of DESALEX Tablets 5mg for treatment of allergic diseases (November 18, 2016)

Main R&D Activities -2 (Feb 3 , 2017 Release)

POC Project (Ph I ~ Ph II)

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 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 , 2017 Release)

Licensing development (preclinical)

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, 2017

Sales, Profit or Loss of each report segment

(Units: ¥ billion)

	Sales	change Y/Y	Profit	change Y/Y
Net Sales (total)	86.8	−2.7	7.3	−7.4
Ethical drugs business	82.5	−2.8	7.1	−7.4
◆Sales of new ethical drugs	64.4	−9.5		
○Japan	64.1	−4.7		
○Overseas	0.3	−4.8		
◆Generic drugs	18.1	6.7		
Healthcare business	4.3	0.1	0	0
Amount of adjustment	—	—	0.2	0

(Note) The details of the Sales Segment have been changed from the first quarter ending March 31, 2017. Following the change, the Pharmaceutical Business comprises New Drugs and Generic Drugs, while the Health Care Business comprises Skincare, Environmental Hygiene and Over the Counter Drugs and Others.

Consolidated Financial Results for the Third Quarter ending March 31, 2017

(unit : ¥million)	Interim term		Third quarter				Full term		
	Sep/2015	Sep/2016	Dec/2015	Dec/2016	Change	% Y/Y	Mar/2016	Mar/2017 (revised forecast)	Mar/2017 (original forecast)
Sales	52,386	54,628	89,469	86,836	-2,633	-2.9%	119,483	115,000	120,000
Ethical drugs business	51,783	51,936	88,559	82,508	-2,805	-3.3%	113,970	109,100	114,000
◆Sales of new ethical drugs	42,229	41,615	73,713	64,407	-9,486	-12.8%	98,506	84,900	92,400
●Japan	41,634	41,272	68,615	64,116	-4,678	-6.8%	92,920	84,000	88,500
●Overseas	594	343	5,098	290	-4,808	-94.3%	5,586	800	3,800
◆Generic drugs	7,393	10,321	11,435	18,101	+6,681	+58.5%	15,465	24,100	21,500
healthcare business	603	2,691	910	4,327	+171	+4.1%	5,512	5,900	6,000
Operating Income	4,099	3,663	14,666	7,313	-7,353	-50.1%	19,636	10,000	14,500
Ordinary Income	4,266	3,921	14,946	7,716	-7,230	-48.4%	19,995	10,400	14,900
Net Income	2,967	2,684	10,831	4,723	-6,108	-56.4%	13,639	6,600	10,700