

# First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2018

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July 31, 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 First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2018

Units: millions of yen	First quarter Jun / 2014	First quarter Jun / 2015	First quarter Jun / 2016	First quarter Jun / 2017	YoY change (%)	Interim term Sep / 2017 (forecast)	YoY change (%)	Year ending Mar / 2018 (forecast)	YoY change (%)
Net sales	26,397	26,567	27,707	<b>26,458</b>	-4.5%	<b>54,600</b>	-0.1%	<b>113,400</b>	-1.7%
Operating income	3,575	2,173	3,244	<b>2,595</b>	-20.0%	<b>5,300</b>	+44.7%	<b>12,100</b>	+16.2%
Ordinary income	3,847	2,316	3,485	<b>2,805</b>	-19.5%	<b>5,600</b>	+42.8%	<b>12,600</b>	+15.9%
Net income	2,681	1,757	2,580	<b>2,393</b>	-7.3%	<b>4,500</b>	+67.6%	<b>9,700</b>	+32.8%

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**[Net sales]** Despite steady growth in Flutiform, a core product, and Desalex, a new product, sales in the new pharmaceutical products in Japan decreased following the expiration of the patent for KIPRES. In contrast, sales in generic drugs increased with the rise in sales of MONTELUKAST AG (KIPRES). As a result, overall net sales were 26,458 million yen, a decrease of 1,249 million yen on a year-on-year basis (down 4.5% year on year).

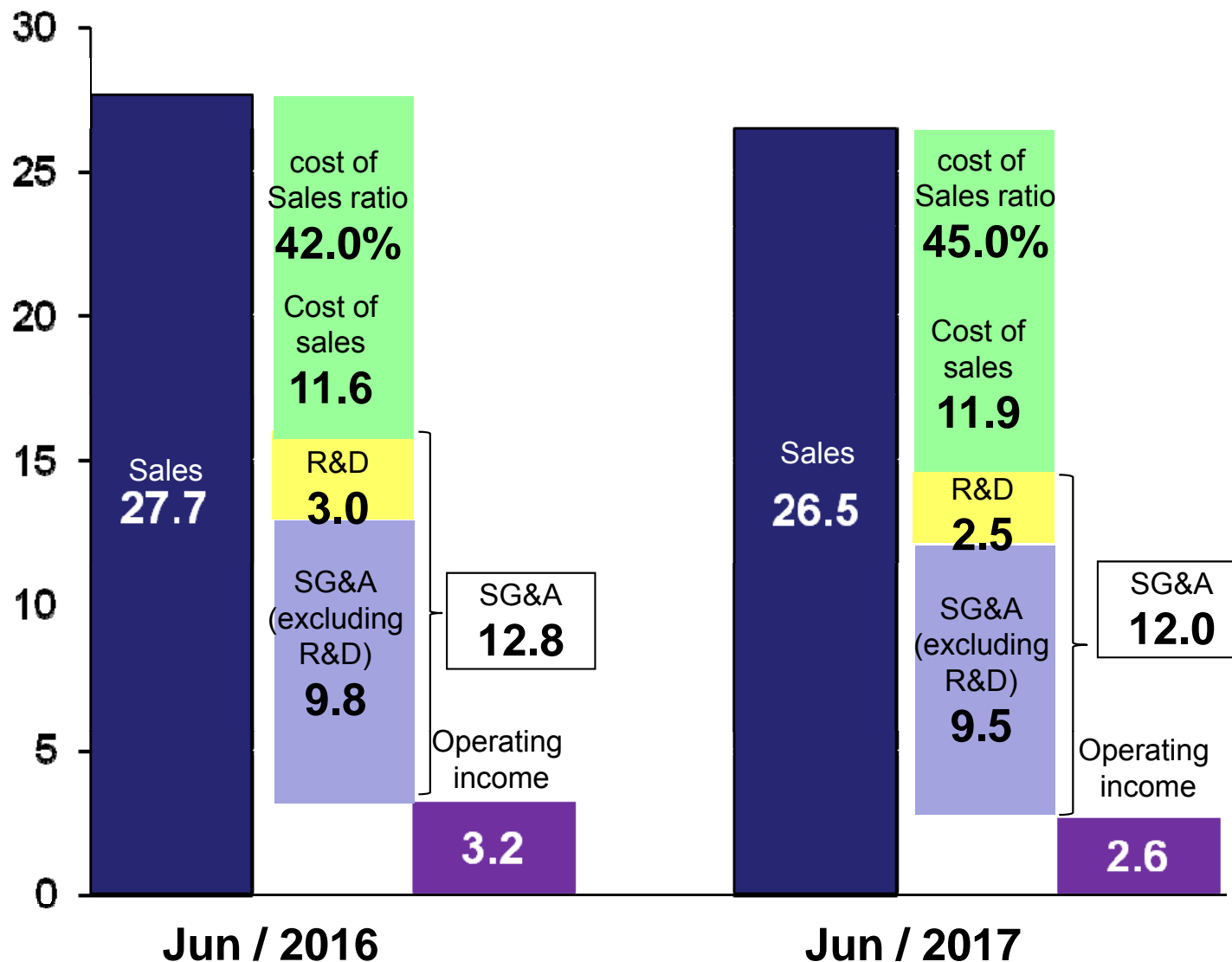
**[Profit]** Gross profit declined by 1,501 million yen on a year-on-year basis mainly due to the decline in the sales of new pharmaceutical products in Japan. SG & A expenses decreased by 852 million yen (including a reduction in R&D expenses of 537 million yen) on a year-on-year basis owing to the promotion of cost reduction. As a result, operating income amounted to 2,594 million yen (down 20.0% year on year), and profit attributable to owners of parent was 2,393 million yen (down 7.3% year on year) partly because of extraordinary profit of approximately 600 million yen associated with the recording of the stocks transfer of Dr. Program Co., Ltd.

## Consolidated Financial Results for the Fiscal Year Ending March 31, 2018(forecast)

The results forecasts for the second half and the full year announced on May 11, 2017 remain unchanged.  
(Progress compared with the forecast for the first half: net sales: 48.5%; operating income: 49.0%)

# Highlights of Business Performance

(Units: ¥ billion)



## Highlight

- Net Sales decreased ¥1.2bln
  - Sales of new ethical drugs decreased
  - Sales of generic drugs increased
- Cost of sales ratio increased 3.0%.
  - **Gross Profit decreased ¥1.5bln**
- SG&A expenses decreased ¥0.8bln
  - R&D expense decreased ¥0.5bln
  - SG&A(excluding R&D) decreased ¥0.3bln

**Operating Income decreased ¥0.6bln**

# Consolidated Financial Results

## for the first Quarter ending March 31, 2018

Year on Year

(¥ billion)	Jun/2016	Jun/2017	change
Net Sales	27.7	26.5	-1.2
Ethical drugs Business	26.4	25.1	-1.3
◆Sales of new ethical drugs	21.8	18.2	-3.6
●Japan	21.7	18.0	-3.7
●Overseas	0.1	0.2	+0.1
◆Generic drugs	4.6	6.9	+2.3
Healthcare Business	1.3	1.3	0
Operating Income	3.2	2.6	-0.6
Ordinary Income	3.5	2.8	-0.7
Net Income	2.6	2.4	-0.2

■ Net Sales **¥26.5bln** (- 1.2)

◆ Ethical drugs business **¥25.1bln** (- 1.3)

● Sales of new ethical drugs **¥18.0bln** (- 3.7)

	Jun/2016	⇒	Jun/2017	
· Flutiform	2.3	⇒	2.8	(+0.5)
· Uritos	2.0	⇒	1.9	(-0.1)
· Desalex※	-	⇒	0.5	(+0.5)
· Kipres	9.9	⇒	5.2	(-4.7)
· Pentasa	4.0	⇒	4.0	( 0)
· Mucodyne	2.4	⇒	2.1	(-0.3)

※Launch(11/2016)

● Sales of new ethical drugs in Overseas **¥0.2bln** (+ 1)

● Sales of Generic drugs **¥6.9bln** (+2.3)

· Increase of MONTELKAST AG sales

◆ Healthcare Business **¥1.3bln** ( 0)

■ Operating Income **¥2.6bln** (-0.6)

◆ Operating Income margin decreased 1.9 percentage points to 9.8%

● Cost of Sales Ratio : increased 3.0 percentage points (42.0%⇒45.0%)

· Sales of new ethical drugs decreased · Sales of generic drugs increased

● R&D Ratio : decreased 1.5 percentage points (10.9%⇒9.4%)

· ¥3.0bln⇒¥2.5bln -¥0.5bln

· The effect of the increased due to Last year of project progress. (KRP-AM1977X)

● SG&A Ratio (excluding R&D expenses) : increased 0.5 percentage points

· ¥9.8bln⇒¥9.5bln ¥-0.3bln

(35.3%⇒35.8%)

· Decrease of sales and general costs and labor costs.

■ Net Income **¥2.4bln** (- 0.2)

· Extraordinary income : Approximately 0.6 billion yen associated with the recording of the stocks transfer of Dr. Program Co., Ltd.

# Main Product Sales Update

( Units: ¥ billion )

Product name		Interim term		Full term		First quarter (April 1 to June 30)				
		Sep/2016	Sep/2017 (forecast)	Mar/2017	Mar/2018 (forecast)	Jun/2016	Jun/2017	YoY change (%)	Progress to Interim term forecast(%)	Progress to Full term forecast(%)
Sales of new ethical drugs (Japan)	Flutiform (Combination drug for asthma treatment)	4.5	<b>5.4</b>	10.1	<b>12.0</b>	2.3	<b>2.8</b>	+20.3%	50.8%	22.8%
	Uritos (Kyorin) (Overactive bladder)	3.8	<b>3.8</b>	7.5	<b>7.6</b>	2.0	<b>1.9</b>	-5.8%	48.3%	24.4%
	Desalex (Antiallergic Agent)	—	<b>0.9</b>	1.0	<b>3.5</b>	—	<b>0.5</b>	—	48.1%	12.8%
	Kipres (LT receptor antagonist)	17.8	<b>10.2</b>	32.7	<b>21.0</b>	9.9	<b>5.2</b>	-47.8%	50.5%	24.5%
	For children	6.3	<b>5.5</b>	14.9	<b>11.1</b>	3.3	<b>3.1</b>	-4.5%	57.0%	28.1%
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	7.9	<b>7.9</b>	15.5	<b>15.6</b>	4.0	<b>4.0</b>	-0.8%	49.6%	25.3%
	Mucodyne (Mucoregulant)	4.4	<b>3.7</b>	9.9	<b>8.3</b>	2.4	<b>2.1</b>	-10.1%	56.5%	25.6%
Generic drugs	MONTELUKAST Tablets "KM"	1.8	<b>4.6</b>	8.2	<b>10.3</b>	—	<b>2.7</b>	—	58.4%	26.0%
Over-the-counter drugs	Milton (Disinfectant)	1.1	<b>1.0</b>	2.2	<b>2.1</b>	0.5	<b>0.5</b>	+6.9%	51.8%	25.3%

# Main R&D Activities -1 (as of July 31 2017)

## Ph III ~ Application submitted

※Changes from the previous announcement(May 11 2017)

Stage		Compound/ Code	Therapy area/Action	Origin	Features	Comments
Japan	Overseas					
Application (4/2017)		※KRP-AM1977X (Oral agent) (Note:1)	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	
Preparing for Application	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) ·License agreement with Merck & Co., Inc., for Asia (4/2017)
Ph III (3/2017)		KRP-116D	Interstitial cystitis	—	Evaluation committee on unapproved or off- labeled drugs with high medical needs “Dimethyl sulfoxide(DMSO)”	
Ph III (6/2017)		※KRP-108P (Note:2)	Anti-asthmatic	(U.K.) Vectura	Expand the indication of Flutiform to pediatric patients	

Note 1: For KRP-AM 1977 X, additional nonclinical studies are required and will be carried out.

Note 2: KRP-108P, a Phase III clinical trial commenced for expand the indication of Flutiform, a compound for asthma treatment, to pediatric patients.

# Main R&D Activities -2 (as of July 31 2017)

## 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 (as of July 31 2017)

## 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 first Quarter Ending March 31, 2018

## Sales, Profit or Loss of each report segment

(Units:¥ billion)	Sales	Year on Year	Profit	Year on Year
<b>total</b>	<b>26.5</b>	<b>−1.2</b>	<b>2.6</b>	<b>−0.6</b>
<b>Ethical drugs business</b>	<b>25.1</b>	<b>−1.3</b>	<b>2.5</b>	<b>−0.7</b>
◆Sales of new ethical drugs	<b>18.2</b>	<b>−3.6</b>		
●Japan	18.0	−3.7		
●Overseas	0.2	0.1		
◆Generic drugs	<b>6.9</b>	<b>2.3</b>		
<b>Healthcare business</b>	<b>1.3</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Amount of adjustment</b>	<b>—</b>	<b>—</b>	<b>0.1</b>	<b>0</b>

# Consolidated Financial Results for the first Quarter ending March 31, 2018

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(Units: ¥million)	Interim term		Full term		First quarter (April 1 to June 30)					
	Sep/2016	Sep/2017 (forecast)	Mar/2017	Mar/2018 (forecast)	Jun/2016	Jun/2017	Change	YoY change (%)	Progress to interim term forecast (%)	Progress to full term forecast (%)
<b>Sales</b>	54,628	<b>54,600</b>	115,373	<b>113,400</b>	27,707	<b>26,458</b>	-1,249	-4.5%	48.5%	23.3%
<b>Ethical drugs business</b>	51,936	<b>51,900</b>	109,566	<b>107,400</b>	26,412	<b>25,112</b>	-1,300	-4.9%	48.4%	23.4%
◆Sales of new ethical drugs	41,615	<b>38,300</b>	84,542	<b>78,900</b>	21,805	<b>18,242</b>	-3,563	-16.3%	47.6%	23.1%
●Japan	41,272	<b>35,700</b>	83,777	<b>75,500</b>	21,741	<b>17,999</b>	-3,742	-17.2%	50.4%	23.8%
●Overseas	343	<b>2,600</b>	764	<b>3,300</b>	64	<b>242</b>	+178	+278.1%	9.3%	7.3%
◆Generic drugs	10,321	<b>13,500</b>	25,024	<b>28,500</b>	4,606	<b>6,870</b>	+2,264	+49.2%	50.9%	24.1%
<b>Healthcare business</b>	2,691	<b>2,700</b>	5,807	<b>5,900</b>	1,295	<b>1,346</b>	+51	+3.9%	49.9%	22.8%
<b>Operating income</b>	3,663	<b>5,300</b>	10,413	<b>12,100</b>	3,244	<b>2,595</b>	-649	-20.0%	49.0%	21.4%
<b>Ordinary income</b>	3,921	<b>5,600</b>	10,874	<b>12,600</b>	3,485	<b>2,805</b>	-680	-19.5%	50.1%	22.3%
<b>Net income</b>	2,684	<b>4,500</b>	7,305	<b>9,700</b>	2,580	<b>2,393</b>	-187	-7.3%	53.2%	24.7%