

# **Interim Term Financial Results Ended September 2017**

**November 7 , 2017  
KYORIN Holdings, Inc.  
President Minoru Hogawa**



## ➤ **Outline of Consolidated Financial Results**

- Trends of mainstay products

## ➤ **Consolidated Financial Results and Forecast**

## ➤ **Status of Development Pipeline**

## ➤ **Topic**

- In Vitro Diagnostics business etc.

# Outline of Consolidated Financial Results

# Outline of Consolidated Financial Results for the Interim Term Ended September 2017

(unit : ¥billion)

	Sep/16	Sep/17	Change	Change(%)	Change (original forecast)
<b>Net Sales</b>	54.6	<b>50.8</b>	-3.8	-7.1	-3.8
<b>Operating Income</b>	3.7	<b>1.4</b>	-2.3	-60.6	-3.9
<b>Ordinary Income</b>	3.9	<b>1.7</b>	-2.2	-56.8	-3.9
<b>Net Income</b>	2.7	<b>1.2</b>	-1.5	-53.8	-3.3

※The results forecasts for the fiscal year ending March 31, 2018 announced on May 11, 2017 are revised.

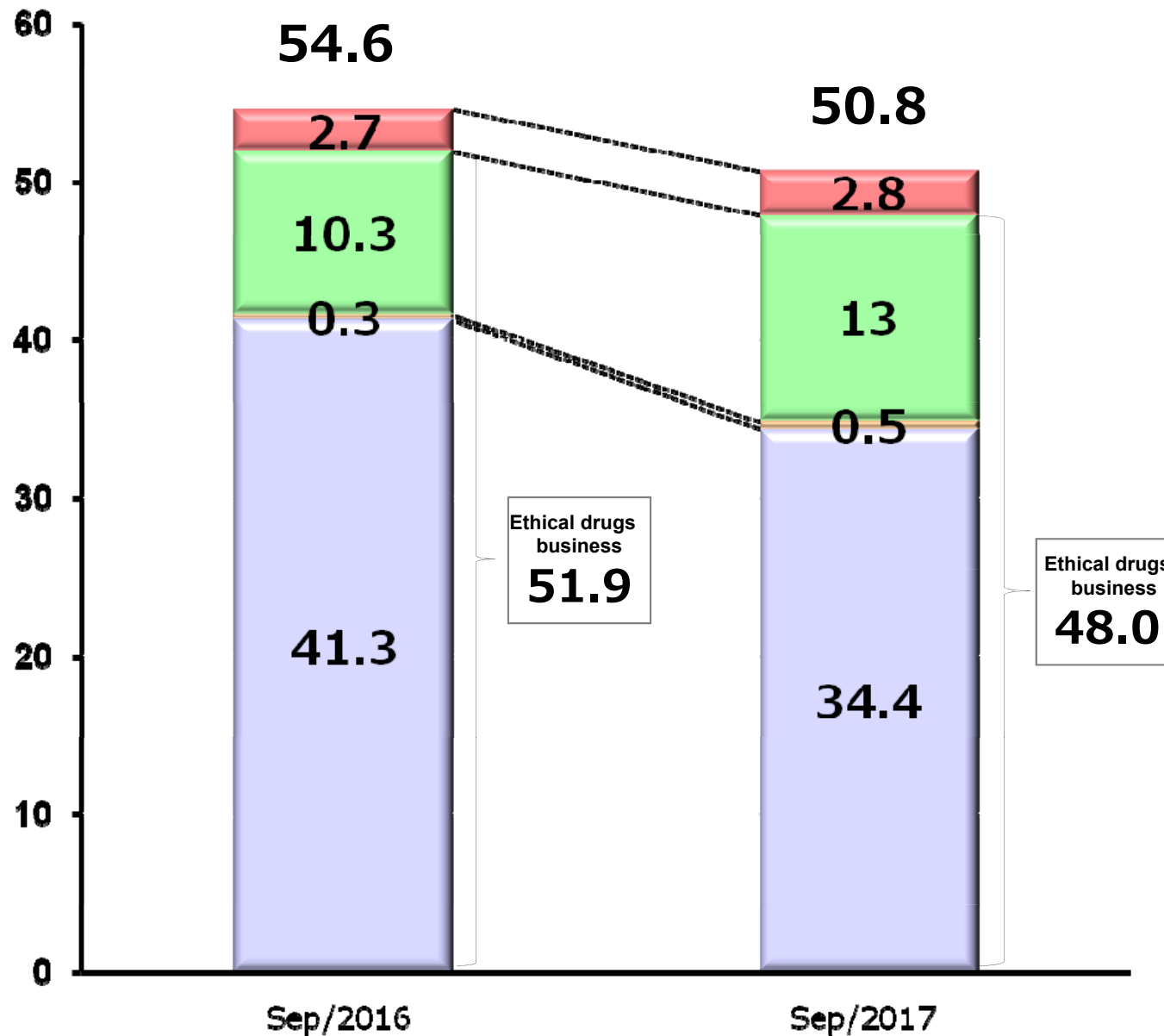
# Segment Sales and Breakdown of Gain and Loss

(unit : ¥billion)

			Sep/16	Sep/17	Change	Change (%)	Change (original forecast)
Net Sales			54.6	<b>50.8</b>	<b>-3.8</b>	<b>-7.1</b>	-3.8
			51.9	48.0	-3.9	-7.6	-3.9
Ethical drugs business	Sales of new ethical drugs		41.6	35.0	-6.6	-16.0	-3.3
		Japan	41.3	34.4	-6.9	-16.5	-1.3
		Overseas	0.3	0.5	+0.2	+52.5	-2.1
	Generic drugs		10.3	13.0	+2.7	+26.0	-0.5
Healthcare Business			2.7	2.8	+0.1	+3.3	+0.1
Cost of Sales			23.8	<b>23.1</b>	<b>-0.7</b>	<b>-2.9</b>	-
SG&A			27.1	<b>26.2</b>	<b>-0.9</b>	<b>-3.5</b>	-
Operating Income			3.7	<b>1.4</b>	<b>-2.3</b>	<b>-60.6</b>	-3.9
Ordinary Income			3.9	<b>1.7</b>	<b>-2.2</b>	<b>-56.8</b>	-3.9
Net Income			2.7	<b>1.2</b>	<b>-1.5</b>	<b>-53.8</b>	-3.3

# Highlights of Business Performance: ① Net sales

(Units: ¥billion)



## 【 Net Sales - 3.8】

### Healthcare Business +0.1

- The distribution of hand hygiene products sales start
- Growth of RUBYSTA and Milton
- Transfer the stocks of the skincare business

## 【 Ethical drugs business - 3.9】

### Generic drugs +2.7

- Increase of MONTELKAST AG sales
- Sales to other companies decreased

### New ethical drugs(overseas)

+0.2

- Increase of Gatifloxacin sales

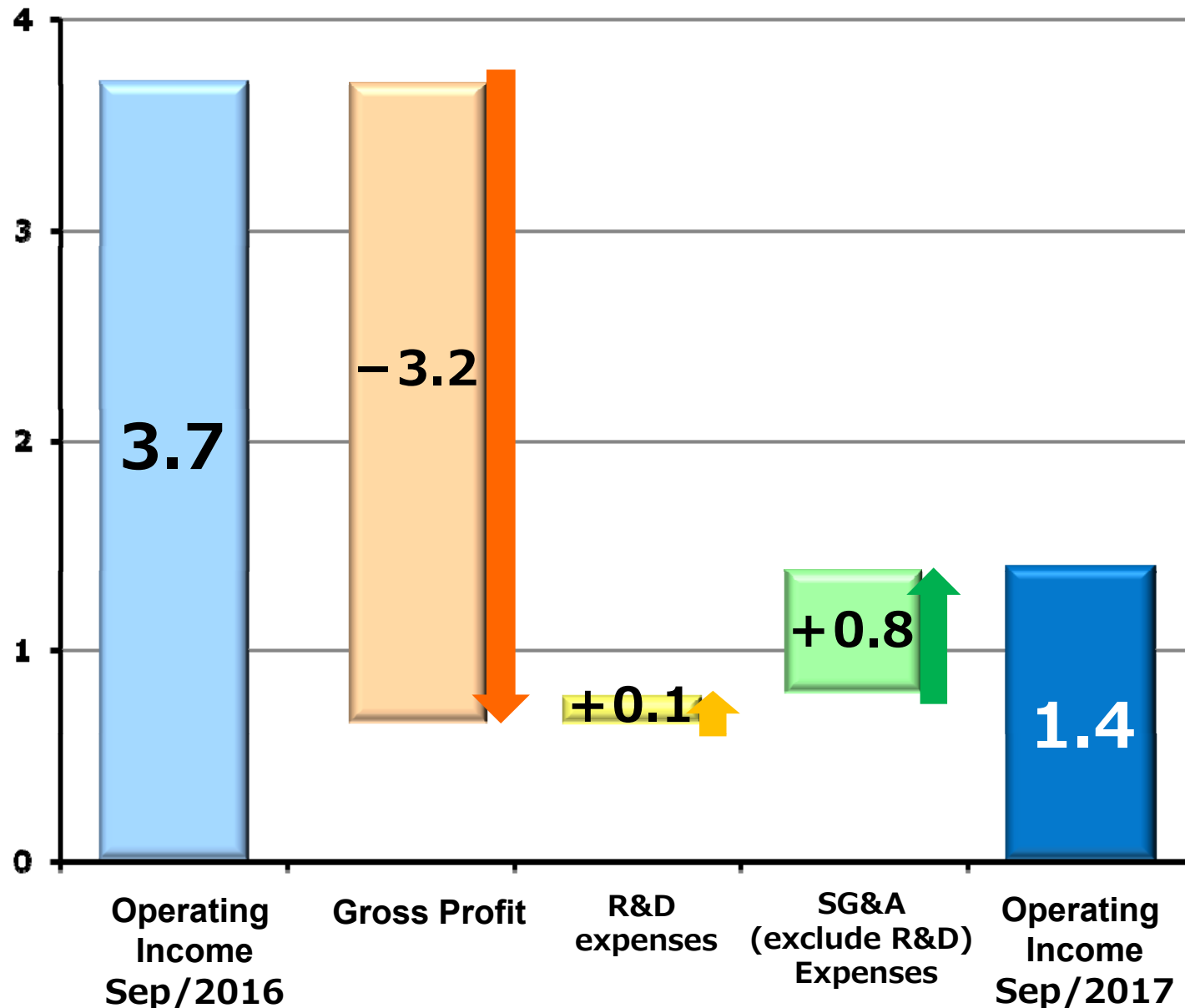
### New ethical drugs(Japan)

-6.9

- Despite steady growth in Flutiform and Desalex sales
- Decreased by the expiration of the patent for KIPRES.
- Decreased in prescriptions of long-listed drugs.

# Highlights of Business Performance : ②Operating Income

(Units: ¥billion)



## 【Operating Income – 2.3】

### Gross Profit decreased

Net Sales decreased ¥3.8billion year on year.

Cost of sales ratio increased 2.0%.

- Decrease of sales of new ethical drugs
- Increase of sales of Generic drugs
- Increase in loss on retirement of inventories, etc.

### R&D expenses is flat year on year

- R&D expenses is flat year on year  
7.3 (Sep/2016) ⇒ 7.2 (Sep/2017)

### SG&A (exclude R&D) Expenses decreased

- Decrease of Labor costs, general expenses  
19.8 (Sep/2016) ⇒ 19.0 (Sep/2017)

# Highlights of Business Performance

: ③Change (original forecast)

(unit : ¥billion)			Sep/16	Sep/17	Change	Change (%)	Change (original forecast)
Net Sales			54.6	<b>50.8</b>	<b>-3.8</b>	<b>-7.1</b>	-3.8
Ethical drugs business	Sales of new ethical drugs		51.9	48.0	-3.9	-7.6	-3.9
	Japan		41.6	35.0	-6.6	-16.0	-3.3
			41.3	34.4	-6.9	-16.5	-1.3
	Overseas		0.3	0.5	+0.2	+52.5	-2.1
	Generic drugs		10.3	13.0	+2.7	+26.0	-0.5
Healthcare Business			2.7	2.8	+0.1	+3.3	+0.1
Cost of Sales			23.8	<b>23.1</b>	<b>-0.7</b>	<b>-2.9</b>	-
SG&A			27.1	<b>26.2</b>	<b>-0.9</b>	<b>-3.5</b>	-
Operating Income			3.7	<b>1.4</b>	<b>-2.3</b>	<b>-60.6</b>	-3.9
Ordinary Income			3.9	<b>1.7</b>	<b>-2.2</b>	<b>-56.8</b>	-3.9
Net Income			2.7	<b>1.2</b>	<b>-1.5</b>	<b>-53.8</b>	-3.3

## ■ Causes of non-attainment of initial forecasts for net sales and profits announced May 11, 2017

Sales	: New ethical drugs(Japan)	·Kipres sales fell short of expectations
	New ethical drugs(Overseas)	·Income relating to out-licensed products fell short of forecast in the first half (progress during the current fiscal year is expected)
	Generic drugs	·Sales to other companies decreased
Cost of sales	: Increase in loss on retirement of inventories, etc.	
Extraordinary loss	: Expenses of around 400 million yen related to the settlement of a lawsuit for violation of US antitrust laws in connection with an out-licensed product (Gatifloxacin eyedrops)	



# Main Product Sales Update

(unit : ¥billion)

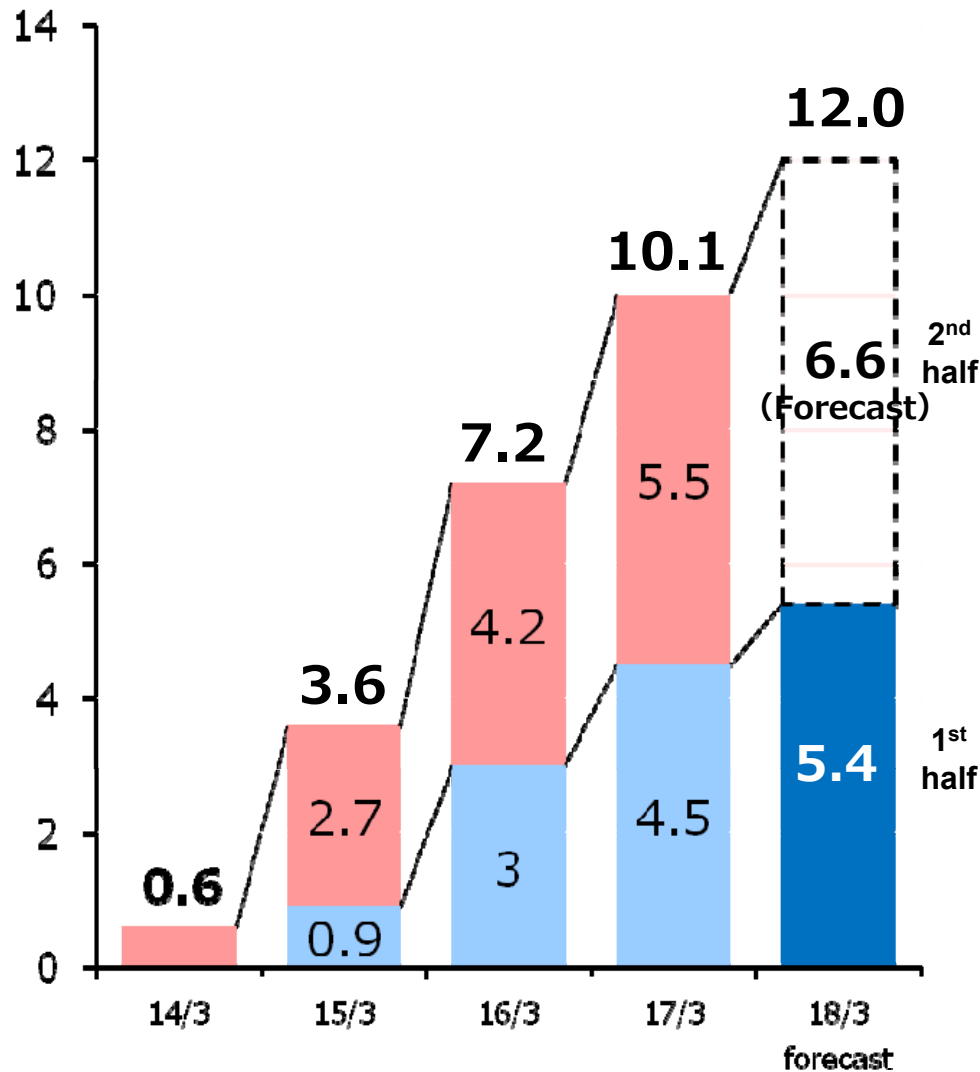
	Sep/16	Sep/17	Change	Change(%)	Change (Original forecast)
<b>Flutiform</b> (Combination drug for asthma treatment)	4.5	<b>5.4</b>	+0.9	+19.6	0
<b>Uritos (Kyorin)</b> (Overactive bladder)	3.8	<b>3.6</b>	-0.2	-4.3	-0.2
<b>Desalex</b> (Antiallergic Agent)	—	<b>0.9</b>	+0.9	—	0
<b>Kipres for adult</b> (LT receptor antagonist)	11.5	<b>3.9</b>	-7.6	-66.2	-0.8
<b>Kipres for children</b> (LT receptor antagonist)	6.3	<b>5.1</b>	-1.2	-18.8	-0.4
<b>Pentasa</b> (Ulcerative colitis and Crohn's diseasetreatment)	7.9	<b>8.0</b>	+0.1	+1.2	+0.1
<b>Mucodyne</b> (Mucoregulant)	4.4	<b>3.9</b>	-0.5	-10.9	+0.2
<b>MONTELUKAST Tablets "KM"</b>	1.8	<b>5.0</b>	+3.2	+177.8	+0.4

# **Trends of mainstay products and Generic drugs**

# ■ New drugs group

## Flutiform 【Anti-asthmatic】

Sales (unit : ¥billion)



### ■ Status in first half 2017

#### ● ICS/LABA market : expand 2%

¥54.3bln (FY16 first half) ⇒ ¥55.2bln (FY17 first half) ※1

#### ● share of Flutiform sales

9.3% (FY16 first half) ⇒ 11.0% (FY17 first half) ※2

### ■ effort for FY2017

#### ● Aim to promote understanding of product characteristics

- Spraying speed slowly
- The agent nicely penetrates and reaches the peripheral airways.

#### ● Expand the indication of Flutiform to pediatric patients (PhⅢ : Jun/2017)

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## ■ New drugs group

# Desalex ( Antiallergic Agent)

- Launch : Nov. 2016
- FY2017 first half sales : ¥0.9 billion  
(forecast : ¥0.9 billion )
- FY2017 Sales (forecast) : ¥3.5 billion  
(FY2016 sales : ¥1.0 billion )



Promoted co-promotion with Kaken Pharmaceutical Co., Ltd. in dermatology area

### ● Improve the visibility of the product:

#### Spread the understanding on its effects and usability

- Has a high affinity for histamine H1 receptors and reliably exhibits an effect
- Half-life is long, and a single daily dose suppresses symptoms for a long time
- Fit patients' lifestyles because it is non-drowsy and unaffected by food

### ● Increase prescriptions

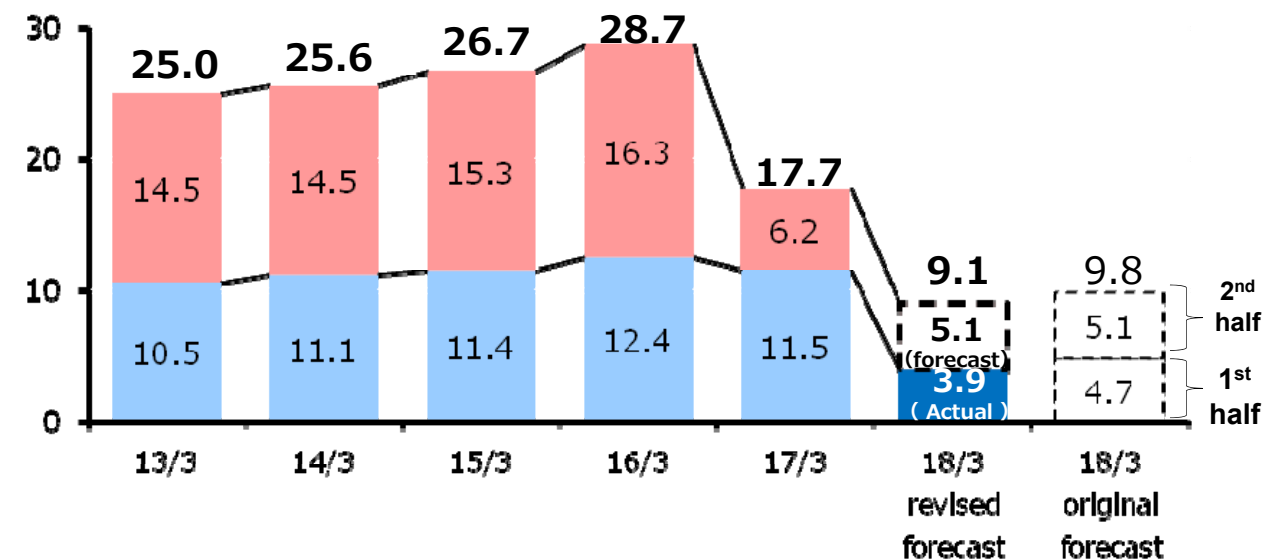
**Aim for dramatic market penetration after the lifting of prescription limitations**

(The prescription restriction will be lifted in December 2017)

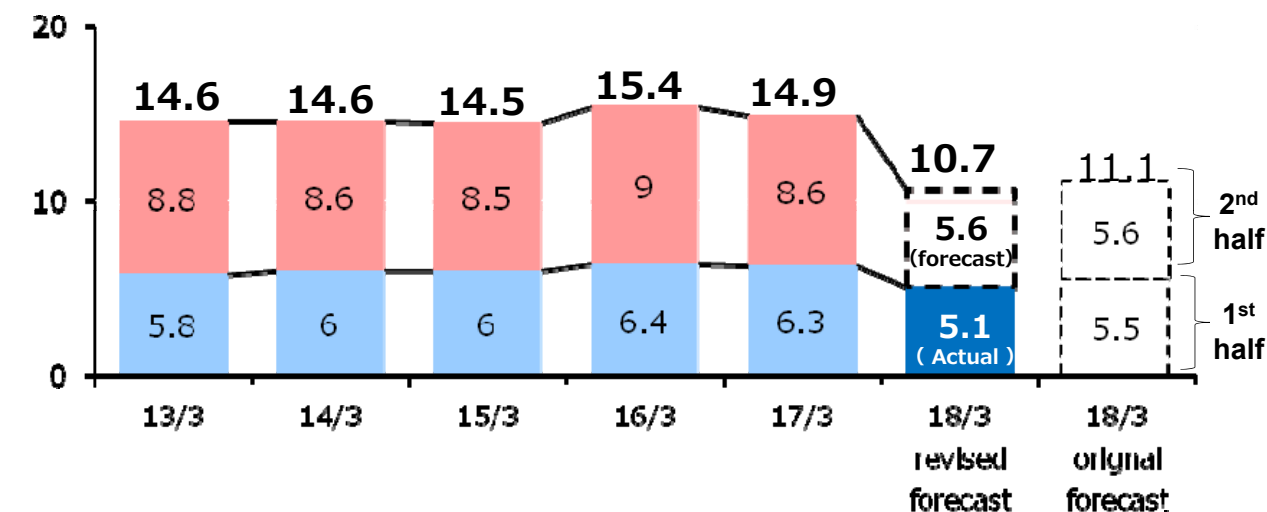
# New drugs group

## Kipres 【Bronchial asthma and allergic rhinitis treatment】

■ Kipres for adult Sales (unit : ¥billion)



■ Kipres for children Sales (unit : ¥billion)



### ■ Status in first half 2017

- LT antagonists market : shrink 23%  
¥56.1bln(FY16 first half) ⇒ ¥43.0bln(FY17 first half) ※1
- share of Kipres sales  
38.2%(FY16 first half) ⇒ 26.5%(FY17 first half) ※2
- About GE of Pediatric Dosage Form
  - GE was released in June 2017
  - GE share is within the assumed range

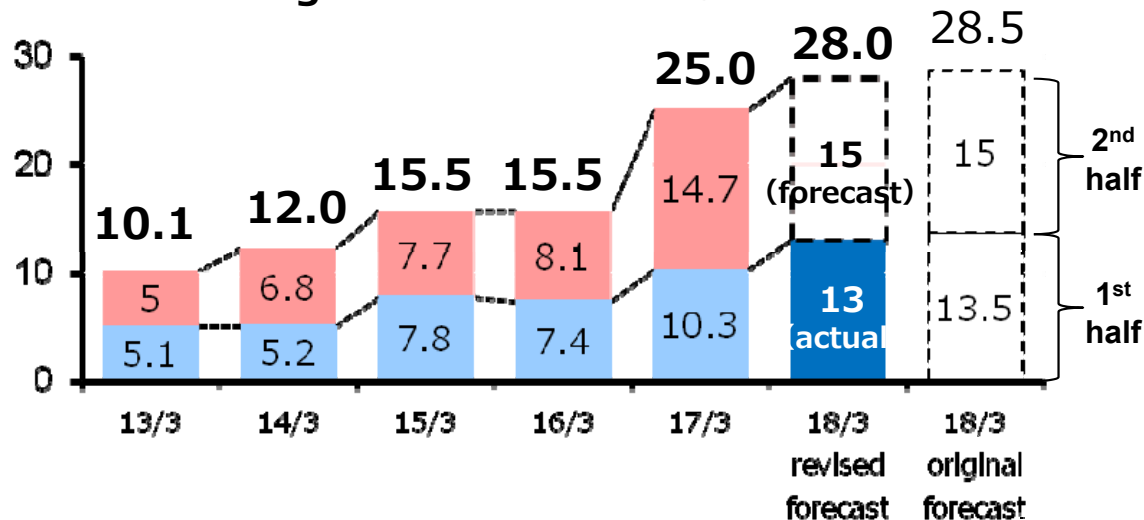
### ■ Effort for FY2017

- Continuously provide accurate information to doctors prescribing the drug
- Promote it with drugs such as Flutiform and 17.7 Desalex in the category of asthma and rhinitis

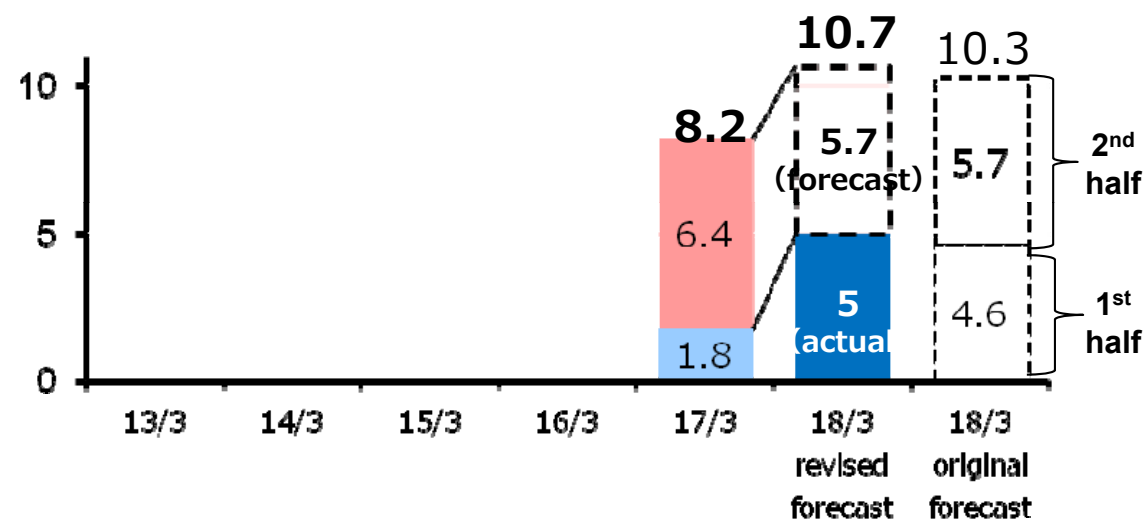
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# ■ Status of Generic Drugs

## ■ Generic drugs Sales (unit : ¥billion)



## ■ Sales of Montelukast AG in sales of generic drugs (unit : ¥billion)



## ■ Status in first half 2017

- Sales of Montelukast AG : ¥5billion  
(Compared to forecasts +¥400 million)
- 2017 June supplementary Item  
= Aripiprazole Telmisartan etc.
- Takaoka Drug Discovery Laboratory  
July of 2017 Start of operations



## ■ Effort for FY2017

- Actions for an authorized generic drug (AG)
  - Maintain a high share of Montelukast AG in the GE market
  - Consider acquiring new AGs  
Mometasone AG approval
- Expand sales of strategic products and Supplementary Items
  - 2017 December supplementary Item  
= Rosuvastatin Olmesartan

# **Consolidated Financial Results Forecast and Dividends**

# Consolidated Financial Results Forecast for the Year Ending March 31, 2018

※The results forecasts for the fiscal year ending March 31, 2018 announced on May 11, 2017 are revised.

(unit : ¥billion)

	FY2016	FY2017 (revised forecast)	Y/Y		FY2017 (original forecast)	Versus the revised forecast	
			Change	Change(%)			
<b>Net sales</b>	115.4	<b>111.3</b>	-4.1	-3.5	113.4	-2.1	
	109.6	105.3	-4.3	-3.9	107.4	-2.1	
<b>Ethical drugs business</b>	<b>Sales of new ethical drugs</b>	84.5	77.2	-7.3	-8.7	78.9	-1.7
	<b>Japan</b>	83.8	74.2	-9.6	-11.4	75.5	-1.3
	<b>Overseas</b>	0.8	3.0	+2.2	+292.7	3.3	-0.3
	<b>Generic drugs</b>	25.0	28.0	+3.0	+11.9	28.5	-0.5
<b>Healthcare Business</b>	5.8	5.9	+0.1	+1.6	5.9	0	
<b>Operating Income</b>	10.4	<b>10.5</b>	+0.1	+0.8	12.1	-1.6	
<b>Ordinary Income</b>	10.9	<b>10.9</b>	0	+0.2	12.6	-1.7	
<b>Net Income</b>	7.3	<b>7.8</b>	+0.5	+6.8	9.7	-1.9	

## ■ Main factors behind revision of forecast

**Net sales** : **New ethical drugs (Japan)** ・Sales forecast for core products (KIPRES, etc.) were lowered .  
**New ethical drugs(Overseas)** ・Income relating to out-licensed products (FPR2 agonist) is expected in the second half of the current fiscal year .  
**Generic drugs** ・Forecast for sales to other companies was lowered.  
**Operating income** : **[Cost of sales]** Loss on retirement of inventories, etc. was revised (reduction expected in the second half)  
**[R&D]** 400 million higher than initially anticipated (original forecast ¥12.6 billion →revised forecast ¥13.0 billion)

## ■ Main factors in year-on-year change

(i) No change in cost of sales ratio year on year; (ii) Decrease in R&D expenses (expected to fall 600 million yen year on year to 13,000 million yen); (iii) Reduction in SG&A expenses (decrease in SG&A ratio (excluding R&D expenses) of around 0.5% ); (iv) gain of approximately 600 million yen as a result of transfer of shares of Dr. Program Co., Ltd. recorded under extraordinary income and class action settlement expenses of approximately 400 million yen relating to *Gatifloxacin eye drops* recorded under extraordinary loss.



# Forecast of Mainstay Product Sales

※The results forecasts for the fiscal year ending March 31, 2018 announced on May 11, 2017 are revised.

(unit : ¥billion)

	FY2016	FY2017 (revised forecast)	Y/Y		FY2017 (original forecast)	Versus the revised forecast
			Change	Change(%)		Change
<b>Flutiform</b> (Combination drug for asthma treatment)	10.1	<b>12.0</b>	+1.9	+19.9	12.0	—
<b>Uritos (Kyorin)</b> (Overactive bladder)	7.5	<b>7.3</b>	-0.2	-1.8	7.6	-0.3
<b>Desalex</b> (Antiallergic Agent)	1.0	<b>3.5</b>	+2.5	+262.3	3.5	—
<b>Kipres for adult</b> (LT receptor antagonist)	17.7	<b>9.1</b>	-8.6	-48.9	9.8	-0.7
<b>Kipres for children</b> (LT receptor antagonist)	14.9	<b>10.7</b>	-4.2	-27.8	11.1	-0.4
<b>Pentasa</b> (Ulcerative colitis and Crohn's diseasetreatment)	15.5	<b>15.6</b>	+0.1	+1.0	15.6	0
<b>Mucodyne</b> (Mucoregulant)	9.9	<b>8.4</b>	-1.5	-14.4	8.3	+0.1
<b>MONTELUKAST Tablets "KM"</b>	8.2	<b>10.7</b>	+2.5	+30.4	10.3	+0.4

# Shareholder Returns

## Basic Policy

-While maintaining the sound financial base, adopt the capital policy ensuring both growth investment and stable return to shareholders.

- In shareholders return, aim for stable dividends.

Dividend per share for fiscal 2017 (estimate): ¥58 (including Year-end dividend of ¥38)

## Dividends

	FY15	FY16	FY17 (forecast)
Dividend per share (Yen)	¥58.00 (Year-end ¥38.00)	¥58.00 (Year-end ¥38.00)	¥58.00 (Year-end ¥38.00)
Consolidated payout ratio(%)	31.8%	59.3%	55.6%

# Status of development pipeline

# Drug Development Pipeline

## The previous announcement (2017/5/12)

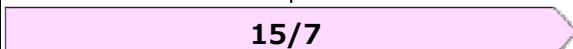
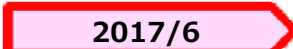



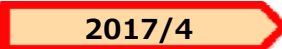


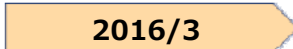



	Product & development code	Ph I	Ph II	Ph III	application	Approval/ Launch
Respiratory	<b>Ad-SGE-REIC</b>	2015/7				
Infections	<b>KRP-AM1977X</b>				2017/4	
	<b>KRP-AM1977Y</b>			2016/3		
Otolaryngological	<b>KRP-209</b>	2015/8				
	<b>Desalex</b>					
Urological	<b>KRP-114V</b>			End of the Ph3	Preparing for Application	
	<b>KRP-116D</b>			17年3月PhⅢ開始		

## 【 Licensing development】

開発コード	導出先	開発段階	特徴
<b>FPR2 agonist program</b>	BMS	Preclinical	FPR-2 agonists that mainly inhibit the migration of neutrophils and exhibit anti-inflammatory action. Therapy area : Non-disclosure
<b>KRP-203</b>	Novartis	Ph I	Sphingosine-1-Phosphate Receptor Agonist . Therapy area : GvHD

# Drug Development Pipeline

 schedule of FY17

	Product & development code	Ph I	Ph II	Ph III	application	Approval/ Launch
Respiratory	<b>Ad-SGE-REIC</b>					
	<b>KRP-108P</b>					
Infections	<b>KRP-AM1977X</b>					
	<b>KRP-AM1977Y</b>					
Urological	<b>KRP-114V</b>					
	<b>KRP-116D</b>					

※ For KRP-AM1977X additional nonclinical studies are required and will be carried out.

※ KRP-209: We therefore decided to discontinue the development.

## 【 Licensing development】

開発コード	導出先	開発段階	特徴
<b>FPR2 agonist program</b>	BMS	Preclinical	FPR-2 agonists that mainly inhibit the migration of neutrophils and exhibit anti-inflammatory action. Therapy area : Non-disclosure
<b>KRP-203</b>	Novartis	Ph I	Sphingosine-1-Phosphate Receptor Agonist . Therapy area : GvHD

# Overactive bladder treatment 「KRP-114V」

## ■Generic name : Vibegron

### 【Positioning】

$\beta$ 3 agonists, the class to which this product belongs, may be widely prescribed together with *anticholinergic drugs in the treatment of overactive bladder.*

### 【 Features 】

- Expectation of high compliance in taking medicine with less side effects than the conventional drugs for overactive bladder
- Reduction of drug interaction as a  $\beta$  3 receptor agonist is expected

※Co-Development and Co-Marketing Agreement with Kissei Pharmaceutical Co., Ltd. affiliate . (3/2016)

## Status of development

### ●Application (2017/9)

#### Clinical Phase III study

Study: A double-blind comparative study for verifying the efficacy and safety of the drug in OAB patients

Result: The drug was shown to be superior to a placebo in primary endpoints and all secondary endpoints.

[Primary endpoints] Average frequency of urination per day

[Secondary endpoints] Average frequency of urinary urgency per day, etc.

**Maximization of efforts for early acquisition of marketing approval and market introduction**

## ■Generic name : Lascufloxacin (LSFX )

### 【 Features 】

- Has a powerful antimicrobial activity compared with other same-class drugs against causative organisms of respiratory and *otorhinolaryngological infections*, including anaerobic bacteria.
- showed a penetration into the excellent lung
- High safety (abnormal blood glucose level, photosensitivity, digestive symptom, etc.) is expected.

Status of development: KRP-AM1977X (Oral agent)

Status of development: KRP-AM1977Y (Injection)

### ●Application(announced in April 2017)

◆High levels of efficacy and safety in the treatment of respiratory and *otorhinolaryngological infections* have been verified and outstanding clinical effectiveness is expected.

As a result of talks with the Pharmaceuticals and Medical Devices Agency (PMDA), a decision to carry out non-clinical studies was made (announced in July 2017).

### ●Clinical trials:Ph3 Results (announced in November 2017)

◆In a phase III clinical study, efficacy and safety in the treatment of community-acquired *pneumonia*, *secondary infection* of chronic respiratory disease, aspiration *pneumonia*, lung *suppuration* and lung *abscess* were verified.

# Tinnitus treatment agent : KRP-209

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## <Tinnitus treatment agent : KRP-209>

### ■ Status of development : **Discontinued development**

We could not confirm the expected efficacy from the results of the POC study (Phase II clinical study) involving a specific patient group with tinnitus, which was conducted again starting from August 2015. We therefore decided to discontinue the development.



# In Vitro Diagnostics business

# Diagnosis business taking advantage of GeneSoC, an ultra-high-speed device for determining the number of gene copies

## ■ Environmental change surrounding infectious diseases

- Promotion of appropriate use of antimicrobial drugs (antibacterial agents, antiviral agents, etc.)
- Increasing needs of diagnostic methods capable of identifying causative organisms in a quick, accurate, and convenient manner in clinical practice

## ■ Product features of GeneSoC, an ultra-high-speed device for determining the number of gene copies

- Rapid gene detection based on ultrafast quantitative PCR \* technology (5 to 6 minutes)
- Highly sensitive detection can be achieved with a trace amount of sample just after infection
- Downsized desktop PCR device in consideration of POCT \*



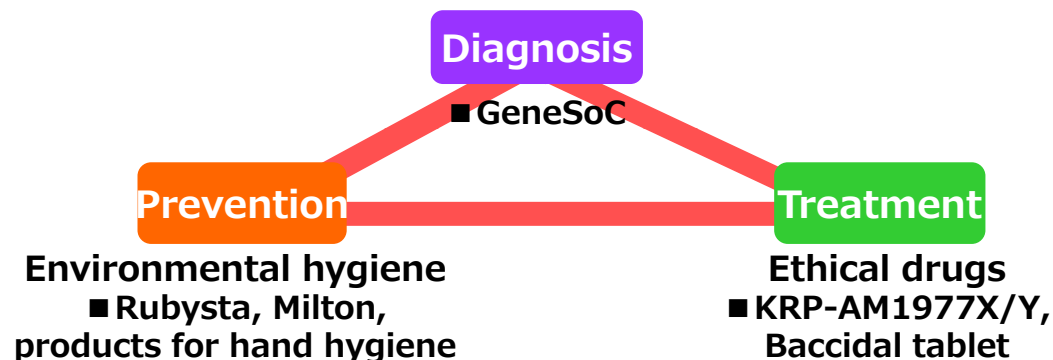
■ GeneSoC, an ultra-high-speed device for determining the number of gene copies

PCR : Polymerase chain reaction. A technique to amplify genes.

POCT : Testing conducted by healthcare professionals beside the subject. With advantages that the testing time can be shortened and the subject can find the testing familiar, it contributes to prompt and appropriate medical care, nursing, and disease prevention as well as health promotion, resulting in improvement in the quality of medical care and the quality of life of the subject.

**To identify bacteria causing infectious diseases through POCT and improve treatment by selecting an appropriate antibacterial drug**

## ■ Our group's efforts in the field of infectious diseases



**In addition to prevention and treatment, we aim to enter the diagnosis-related business to increase our presence in the field of infectious disease**

# Consolidation of Group Production Functions

# Consolidation of Group Production Functions

At the leveling of capacity utilization and the efficient use of assets, and the building of a competitive Group production structure for consistently providing high-quality products at low cost.

**KYORIN Pharmaceutical**

Noshiro Plant(Akita Pref.)



**KYORIN Rimedio**

Inami Plant(Toyama Pref.)



**KYORIN Pharmaceutical Facilities**

( Shiga Pref.)



**Establishment of a new manufacturing Subsidiary (October/2017)  
The plans to consolidate production functions in April 2018.**

【Profile of new manufacturing subsidiary】

- Name : KYORIN Pharmaceutical Group Facilities Co., Ltd.
- Head office : 6,Kanda Surugadai 4-Chome Chiyoda-ku,Tokyo
- Establishment date : October 2,2017