

# **Interim Term Financial Results Ended September 2013**

**November 6 , 2013  
KYORIN Holdings, Inc.  
President Masahiro Yamashita**



- Outline of Consolidated Financial Results for the Interim Term Ended September 2013
- Trends of mainstay products and Status of generic drugs
- Status of development pipeline
- Environmental Hygiene business
- Consolidated Financial Results Forecast for the Year Ending March 31 2014 and Dividends

**Outline of Consolidated Financial Results  
for the Interim Term Ended September 2013**

# Outline of Consolidated Financial Results for the Interim Term Ended September 2013



(unit : ¥100mil)

	Sep/12	Sep/13	Change (actual)	% Y/Y	Change (forecast)
Net Sales	480	<b>509</b>	<b>+ 29</b>	<b>+ 6.0</b>	<b>- 6</b>
Operating Income	63	<b>62</b>	<b>- 1</b>	<b>- 0.9</b>	<b>- 5</b>
Ordinary Income	66	<b>65</b>	<b>- 1</b>	<b>- 1.2</b>	<b>- 5</b>
Net Income	43	<b>44</b>	<b>+ 1</b>	<b>+ 2.4</b>	<b>- 2</b>

# Segment Sales (Consolidated)

(unit : ¥100mil)

		Sep/12	Sep/13	Change (actual)	% Y/Y	Change (forecast)
<b>Net Sales</b>		480	<b>509</b>	+ 29	+ 6.0	- 6
		470	<b>500</b>	+ 30	+ 6.4	- 8
<b>Ethical drugs business</b>	<b>Sales of new ethical drugs</b>	397	<b>429</b>	+ 32	+ 8.0	- 6
	<b>Japan</b>	387	<b>417</b>	+ 30	+ 7.9	- 6
	<b>Overseas</b>	10	<b>12</b>	+ 2	+ 13.5	+ 1
	<b>Generic drugs</b>	51	<b>52</b>	+ 1	+ 2.5	+ 1
	<b>Over-the-counter drugs</b>	23	<b>20</b>	- 3	- 12.9	- 2
<b>Healthcare Business</b>		9	<b>8</b>	- 1	- 11.9	+ 1

	Explanation of Variances
<b>new ethical drugs(Japan)</b>	<ul style="list-style-type: none"> <li>•influence of KYORIN Pharmaceutical Facilities sales (6 months)</li> <li>•increase of main product (Kipres, Pentasa etc.) . Fall below forecast(mainly Kipres)</li> <li>•increase of royalty (licensing out product)</li> </ul>
<b>new ethical drugs(overseas)</b>	sales of Gatifloxacin increased effect of exchange rate (sales of Allergan: FY12 2Q \$44MM→FY13 2Q \$35MM)
<b>Generic drugs</b>	increase of health insurance pharmacy market's sales
<b>Over-the-counter drugs</b>	otc and sales others decreased
<b>Healthcare Business</b>	sales decreased because of concentration of distribution route to mail order system

# Breakdown of Gain and Loss

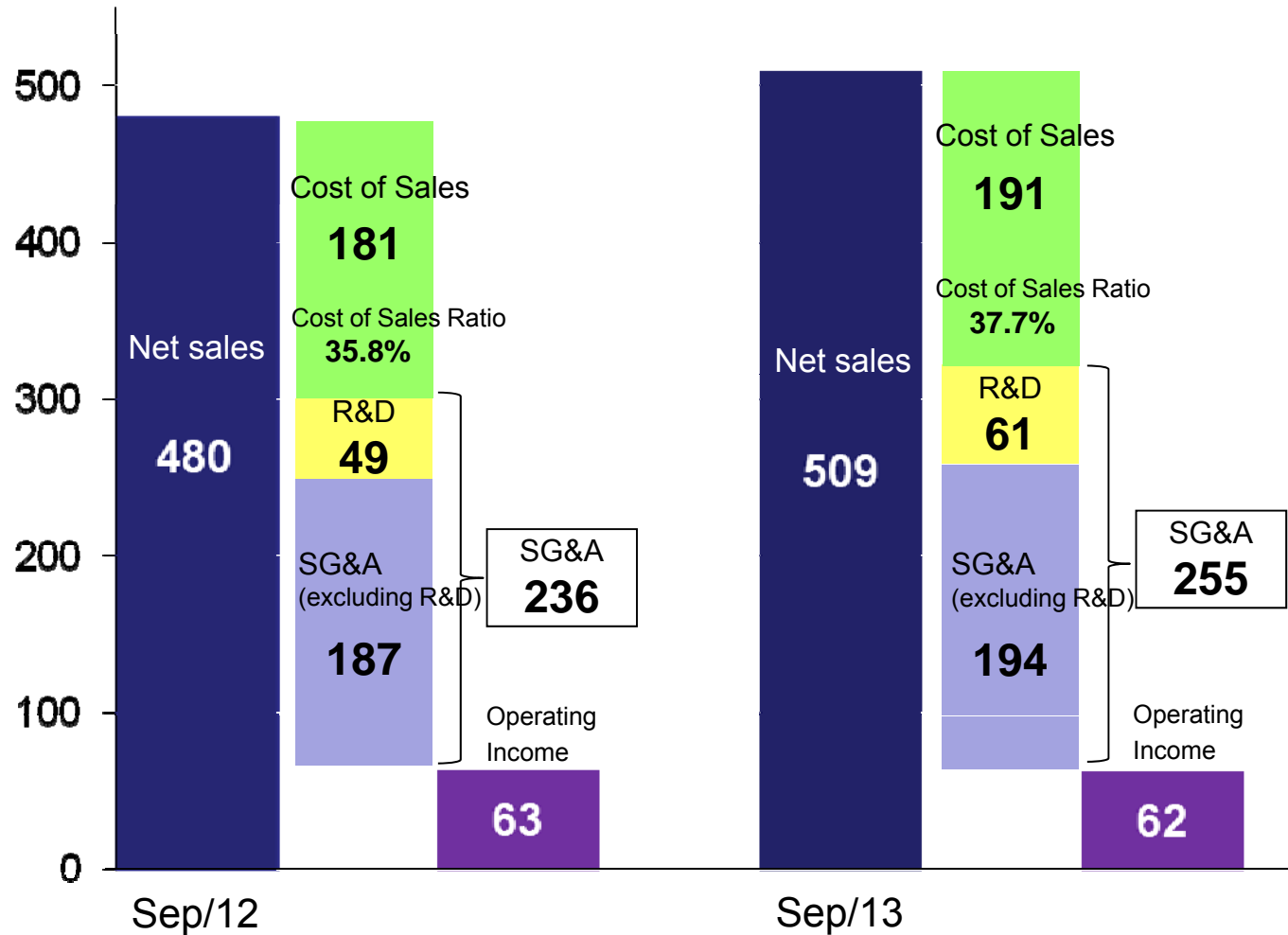
(unit : ¥100mil)

	Sep/12	Sep/13	Change (actual)	% Y/Y	Change (forecast)
Net Sales	480	509	+ 29	+ 6.0	- 6
Cost of Sales	181	191	+ 10	+ 5.5	-
SG&A	236	255	+ 19	+ 8.3	-
R&D expenses	49	61	+ 12	+ 25.1	+ 4
SG&A expenses	187	194	+ 7	+ 3.9	-
Operating Income	63	62	- 1	- 0.9	- 5
Ordinary Income	66	65	- 1	- 1.2	- 5
Net Income	43	44	+ 1	+ 2.4	- 2

	Explanation of Variances
Operating Income	<ul style="list-style-type: none"> <li>➢ <u>gross profit</u></li> <li>• Increased ¥1.9bln (increase of sales , cost of sales ratio remained almost the same y/y).</li> <li>• Fall below forecast (mainly Kipres)</li> <li>➢ <u>R&amp;D expenses</u></li> <li>• progress of the pipeline (KRP-209 Ph2a) (y/y +¥1.2bln, forecast + ¥0.4bln)</li> <li>➢ <u>SG&amp;A Expenses (excluding R&amp;D Expenses)</u></li> <li>• Increased + 0.7bln , Fall below forecast (reduction of cost)</li> </ul>

# Highlights of Business Performance

(Units: ¥100mil)



## Highlight

Net Sales increased ¥2.9billion year on year

- increase of Japan new ethical drugs sales
- effect of KYORIN pharmaceutical Facilities sales

## Highlight

Cost of Sales ratio remained almost the same level as the previous year.

**Gross Profit increased ¥1.9billion year on year**

## Highlight

SG&A expenses increased ¥1.9billion year on year.

- R&D expenses increased ¥1.2billion (progress of the pipeline)
- SG&A(excluding R&D) increased ¥0.7billion

**Operating Income decreased ¥0.1 billion year on year.**

# Mainstay Product Sales

(unit : ¥100mil)

	Sep/12	Sep/13	Change (actual)	% Y/Y	Change (forecast)
<b>Kipres</b>	163	<b>171</b>	+ 8	+ 5.0	- 6
<b>Mucodyne</b>	83	<b>82</b>	- 1	- 0.6	+ 2
<b>Pentasa</b>	90	<b>94</b>	+ 4	+ 4.8	+ 1
<b>Uritos</b>	36	<b>37</b>	+ 1	+ 2.8	- 2
<b>Gatifloxacin (Over seas)</b>	9	<b>10</b>	+ 1	+ 14.1	+ 1

[ For reference ]

Year on year rate of sales for medical institution  
( calculated based on drug price )

Kipres	+ 8.5%
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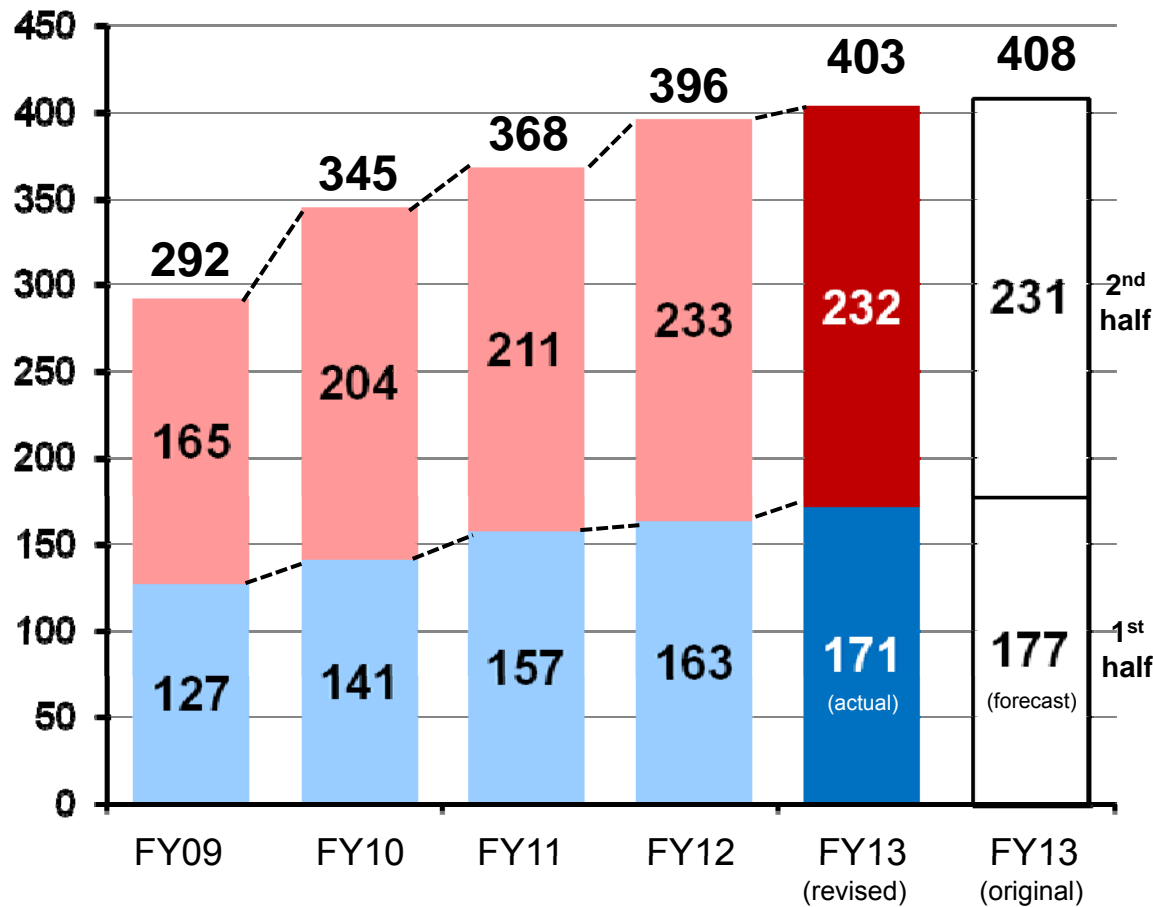


**Trends of mainstay products and  
Status of generic drugs**

# Kipres [Bronchial asthma and allergic rhinitis treatment]



(unit : ¥100mil)



## ■initiatives in FY2013

### ◆LT antagonists market : expand 5%

¥54.8bln (FY12 first half)    ¥57.5bln (FY13 first half)    1

### ◆share of Kipres sales

34.5% (FY12 first half)    35.7% (FY13 first half)    2

[for reference] increase decrease rate of Kipres sales y/y  
 · sales of Kipres : +5.0%  
 · sales of Kipres : +8.5%    3  
 (for medical institution)

■Establish position as base drug for treatment of allergic rhinitis(perennial and seasonal) and growth in new prescriptions

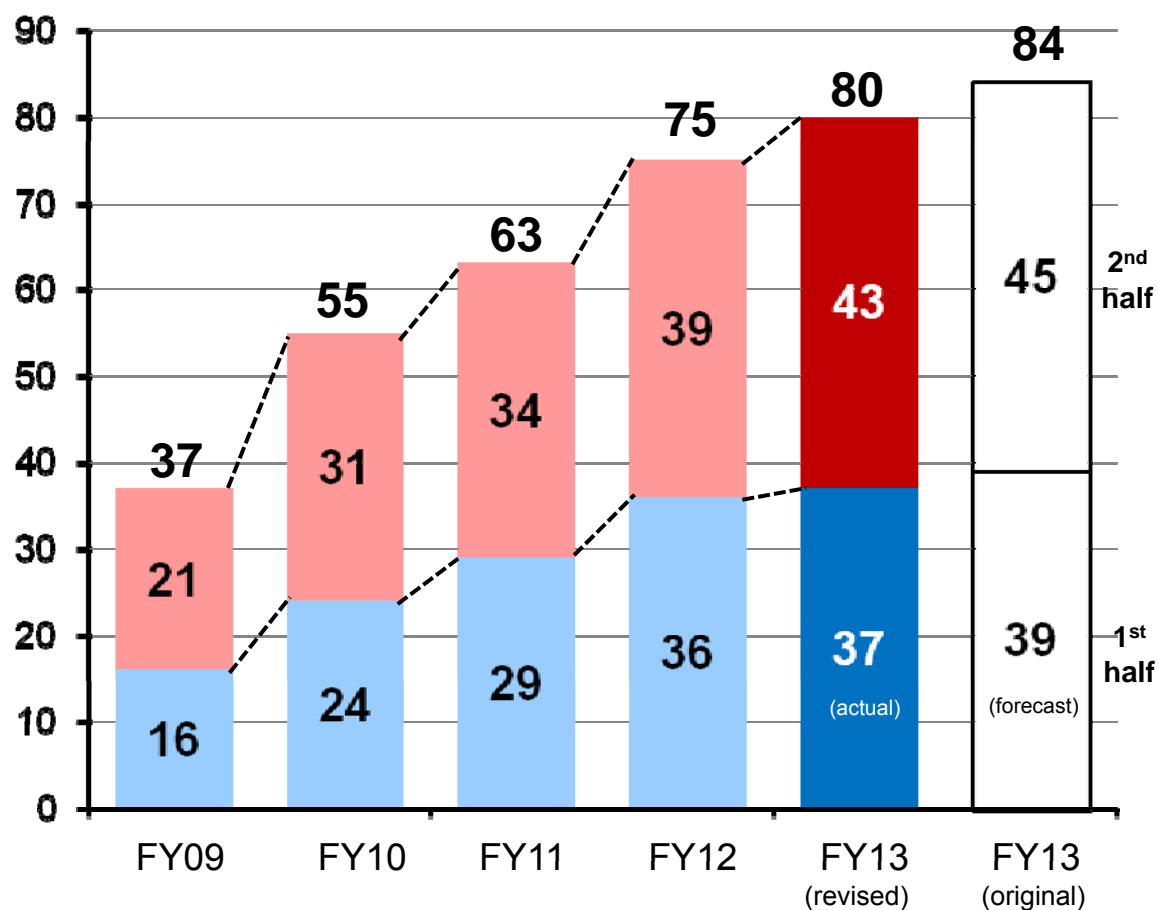
■Further promote prescription

- asthma with rhinitis
- viral-induced asthma

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# Uritos 【Overactive bladder】

(unit : ¥100mil)



## ■initiatives in FY2013

### ◆OAB market : expand 9%

¥33.5bln (FY12 first half)    ¥36.6bln (FY13 first half)    1

### ◆share of Uritos sales

11.6% (FY12 first half)    11.0% (FY13 first half)    2

### ■Uncovering potential markets

- FY11 : potential patient 9million people / consultation rate 28%
- FY12 : potential patient 9.1million people / consultation rate 29%

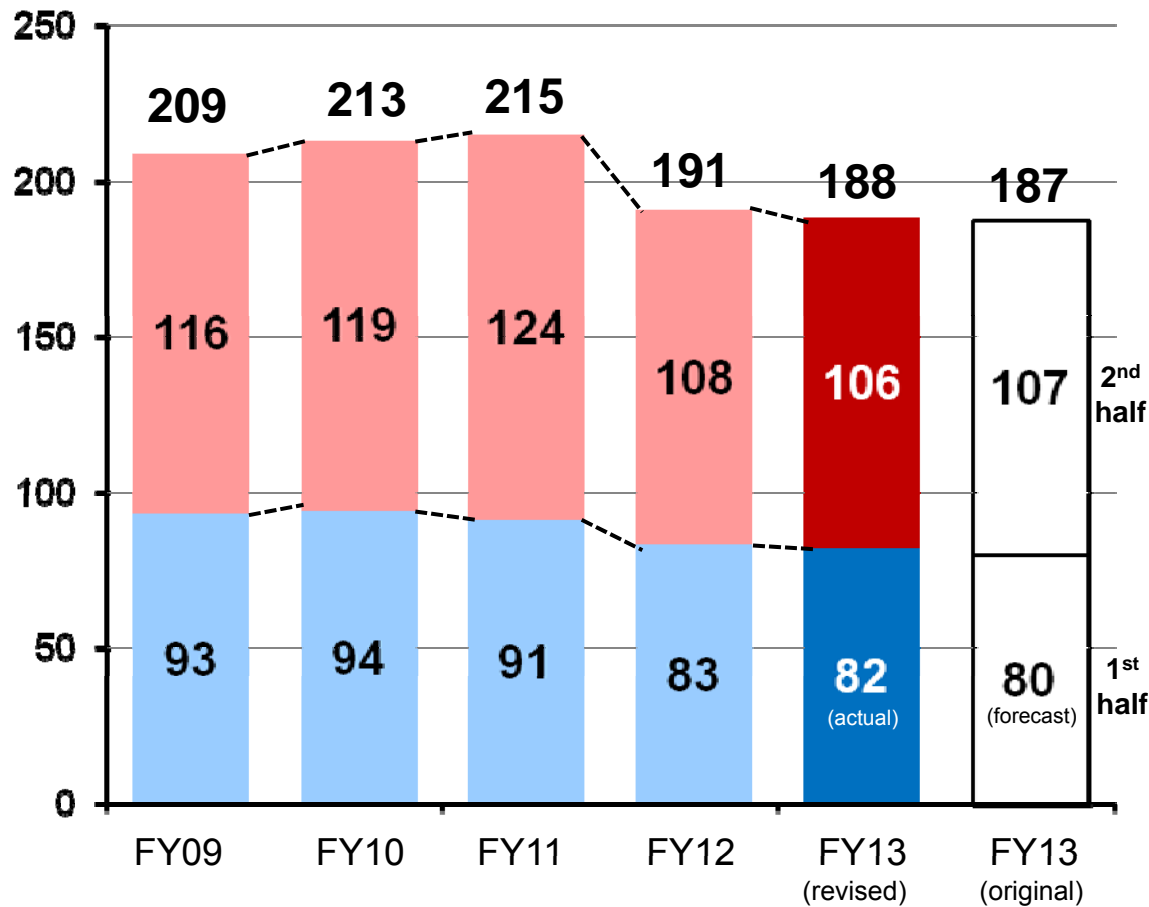
### ■Enlargement of Quantity

- Easy to use for OAB patient
- Good balance of efficacy and safety
- Flexible dosage

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# Mucodyne 【 Mucoregulating drug 】

(unit : ¥100mil)



## ■ initiatives in FY2013

### ◆ share of Mucodyne sales in expectorant market

45.8% (FY12 first half)    45.8% (FY13 first half)    1

· share of generic (Carbocisteine)

5.9% (FY12 first half)    6.8% (FY13 first half)    2

### ■ Maximize uptake and prescriptions of new formulation 「DS50%」

· growth in new prescriptions for childhood inflammation of the upper airway and geriatric respiratory disorder

### ■ Increase prescriptions for chronic conditions based on EBM

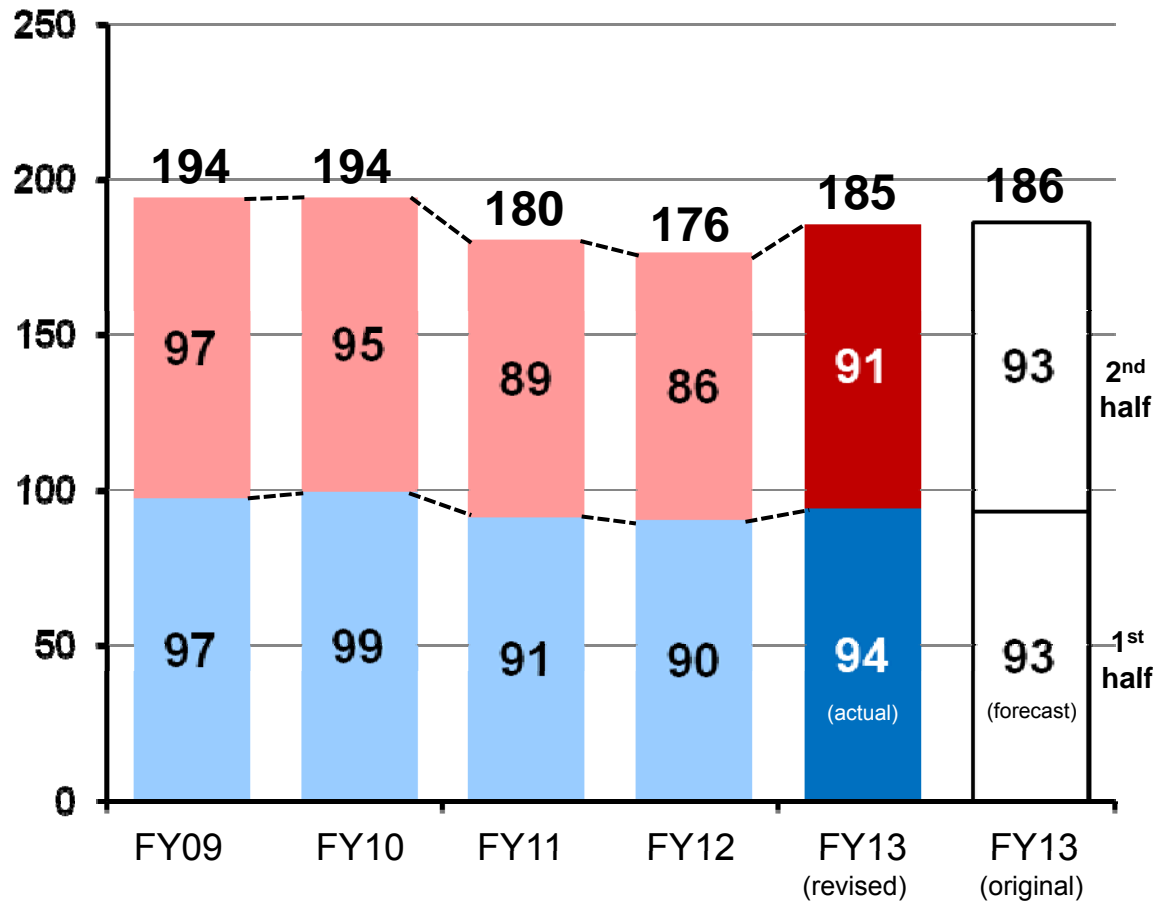
bronchial asthma , chronic bronchitis , chronic sinusitis

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# Pentasa [ Ulcerative colitis and Crohn's disease treatment ]



(unit : ¥100mil)



## ■ initiatives in FY2013

### ◆ market (Mesalazine etc.) : expand 11%

¥16.7bln (FY12 first half)    ¥18.6bln (FY13 first half)    1

### ◆ share of Pentasa sales

58.1% (FY12 first half)    53.9% (FY13 first half)    2

### ■ Establish basic prescription for ulcerative colitis.

- active period : prescription of 4g twice a day
- remission period : prescription of 2g once a day

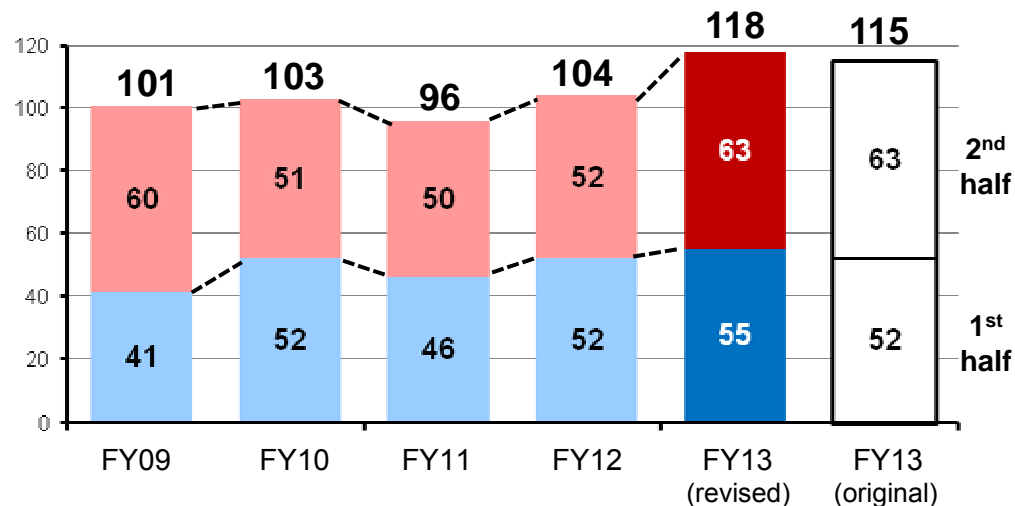
### ■ new drug formulation : suppositories

- sales : 9/2013 actual ¥0.5bln , 3/2014 forecast ¥1.2bln
- launch : 6/2013

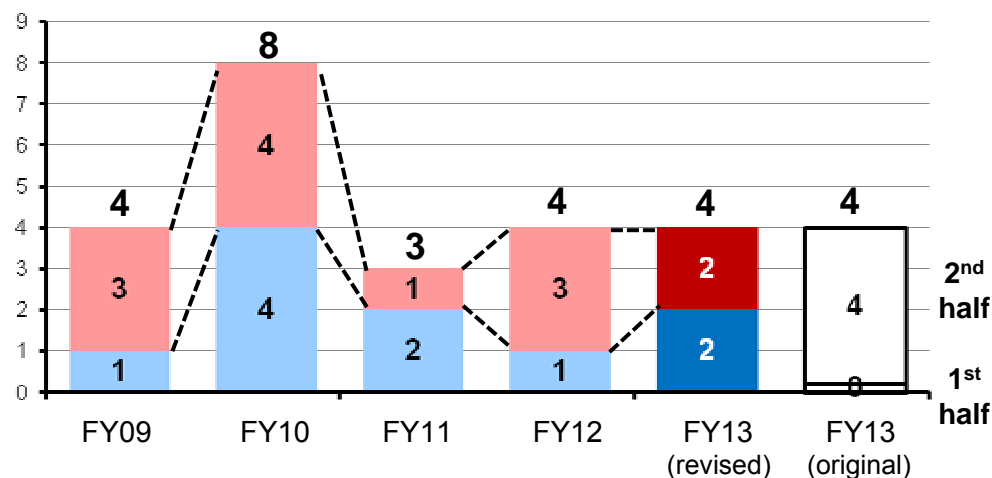
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# Status of Generic Drugs

sales (unit : ¥100mil)



operating Income (unit : ¥100mil)



## ■initiatives in FY2013

### ➤ Promotion of Domestic and overseas alliances

- Promote in-house development and contracting work

### ➤ Strengthen alliances with sales initiatives of KYORIN Pharmaceutical and KYORIN Rimedio

### ◆ Net sales

#### · increase of strategic products

Amlodipine , Donepezil etc.

#### · Market Large-scale Supplementary Items and Reach Objectives

[previous Supplementary Items(4 components , 8 items)]  
fexofenadine , Risedronic acid etc.

[coming Supplementary Items(4 components , 7 items)]  
Pitavastatin Ca , Valaciclovir etc.

### ◆ Operating income

#### · reduce cost of sales















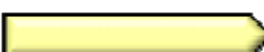







Aim for lower purchase prices for key ingredients

#### · promotion of collaborative development

cost reduction by co-developing and promote contracting work

## **Status of development pipeline**

# Drug Development Pipeline: Progress in FY2013

	Product & development code	Ph	Ph	Ph	application	Approval/ Launch
Respiratory	Fultiform(KRP-108)					 
	KRP-AB1102					
	KRP-AB1102F					
Urological	<b>KRP-EPA605</b>					
Otolaryngological	Kipres Bronchial asthma (1 ~ below the age of 15)					
	KRP-209					
Infections	KRP-AM1977X					
	KRP-AM1977Y					
IBD	Pentasa(UC) suppository					
	KRP-203					



progress in FY13 first half



schedule of FY13 second half



# Flutiform : a combination drug for asthma

- Approved on September 2013 (the drug price in Japan is due to list on November)  
In oversea markets : launched in 12 European countries by Mundi pharma.
- [Asthma Prevention and Management Guideline 2012,Japan] (Japanese Society of Allergology)

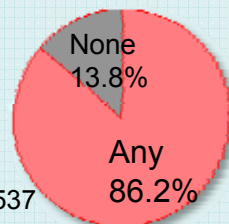
		Step 1	Step 2	Step 3	Step 4
CONTROLLER OPTIONS	Basic treatment	Inhaled glucocorticosteroids	Inhaled glucocorticosteroids long-acting β2-agonist	Inhaled glucocorticosteroids long-acting β2-agonist <b>Flutiform</b>	Inhaled glucocorticosteroids long-acting β2-agonist
		leukotriene receptor antagonist	leukotriene receptor antagonist <b>KIPRES</b>	leukotriene receptor antagonist	leukotriene receptor antagonist
		sustained-release theophylline	sustained-release theophylline	sustained-release theophylline	sustained-release theophylline Anti-IgE treatment oral glucocorticosteroid
	Add-on	anti-allergic	anti-allergic	anti-allergic <small>(Asthma Prevention and Management Guideline 2012,Japan(JGL),P130,modification)</small>	anti-allergic

About 2.8 million patients

About 2.8 million patients

Even if it has taken controller, 60 to 80% of the patients (treatment steps2~4) are Partly Controlled

In (changes in temperature) some risk factors  
The proportion of patients asthma symptoms / exacerbations occurred



Survey of adult asthma patients with 2-4 treatment step  
( Study was confined to patients has continued taking controller drugs have a regular examination)

Source: Kazuoakiyama Allergology & Immunology, 19, 1120-1127 (2012)

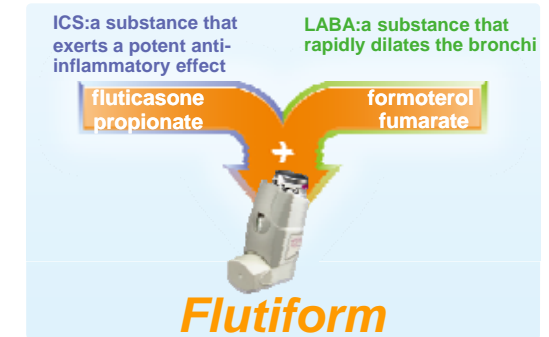
## About Partly Controlled ( One or more features of Following items )

- Nocturnal/Daytime symptoms : More than once/week
- Need for reliever/ rescue treatment : More than once/week
- Limitations of activities : Any
- Lung function (PEF or FEV<sub>1</sub>) : < 80% predicted or personal best (if known)
- circadian change of PEF : < 20%
- Exacerbations : One or more/year

# Flutiform : a combination drug for asthma

## ➤ About Flutiform :

1. Materializes ideal combination of potent ICS and rapid, long-lasting LABA.  
(Best Combination)
2. offers convenience and better compliance of the patients.
3. easy to use : MDI device offers several advantages such as reproducible doses per actuation and suitability to patients with lowered respiratory effort.



## ➤ Enlightenment of proper inhalation technique:

1. Provide inhalation guidance thoroughly (doctor , pharmacist , health-care provider)
2. enrich Informed consent tool

Understanding of product profile / Appropriate inhalation  
Realize the effect

**Aim for early spread in the market**

# KRP-EPA605 : Status of Development

## ■KRP-EPA605 (for the treatment of overactive bladder)

- prostaglandin EP1 receptor antagonist
- different mechanism of action from existing therapies( $\beta$ 3 agonists and anticholinergic drugs)

## ■Status of Development

- Phase I (Oct. 2013)
- Co-development with KISSEI PHARMACEUTICAL

**aim to early approval of this drug**

# about new Development Research Laboratories



location : 1848, Nogi, Nogi-machi, Shimotsuga-gun, Tochigi  
commencement of construction : Jan / 2014  
completion of construction : Aug / 2015  
commence operations : Oct / 2015

## **Environmental Hygiene business**

# Environmental Hygiene business

■existing product : preserve and expand Disinfectant 「Milton」 (unit : ¥100mil)

	FY08	FY09	FY10	FY11	FY12	FY13 (forecast)	FY13 (1 <sup>st</sup> half)
sales	18	19	19	19	20	20	10



■new product : promote spread of Multi-purpose disinfectant cleaner 「RUBYSTA」

Aim at expanding use through introduction and standardization at hospitals while focusing on Category-1 facilities eligible for NHI points for measures against infections.

(forecast of FY13 : ¥0.3bln)

(Note) Category-1 facilities eligible for NHI points for measures against infections: Those facilities that satisfy the requirements, such as the appointment of a full-time HAI manager and the setup of a department involved in the prevention of infections.



■expand product lineup

kit product for helping prevent infection

- kit product for helping prevent from pandemic infection such as new strain of influenza etc. (「Dupont™ Tyvek®」 protective suit is manufactured by Dupont USA)
- launch : Jul / 2013

Medical institutions, as designated public corporations, shall prepare a manual for medical care continuation and also stockpile protective kits and other items individually according to the MHLW guidelines.



kit product of Multi-purpose disinfectant cleaner 「RUBYSTA」 for vomit

- reduce a risk of infection(norovirus) from vomit and to cleanup
- preparing for launch



**Consolidated Financial Results Forecast  
for the Year Ending March 31 2014 and  
Dividends**

# Consolidated Financial Results Forecast for the Year Ending March 31, 2014



(unit : ¥100mil)

	Mar/13	Mar/14 Revised forecast	Change	% Change	Change from original forecast
<b>Net Sales</b>	1,070	1,126	+ 56	+ 5.2	- 4
<b>Ethical drugs business</b>	1,052	1,109	+ 57	+ 5.5	- 4
<b>Healthcare(skincare)     Business</b>	19	17	- 2	- 9.0	0
<b>Operating Income</b>	179	182	+ 3	+ 1.4	- 4
<b>Ordinary Income</b>	187	188	+ 1	+ 0.7	- 4
<b>Net Income</b>	124	124	0	- 0.2	- 3

	change (y/y)	change (forecast)	Explanation of Variances	
	+ 56	- 4		
Net sales	new ethical drugs (Japan)	+ 45	- 7	<ul style="list-style-type: none"> <li>•influence of KYORIN Pharmaceutical Facilities sales</li> <li>•increase of main product (Kipres, Pentasa etc.) . Fall below forecast(mainly Kipres)</li> <li>•increase of royalty (licensing out product)</li> </ul>
	new ethical drugs (Overseas)	- 1	+ 2	Expenses associated with the income due to transfer of Pekiron assets were posted in the previous year.
	Generic drugs	+ 13	+ 3	sales increased at KYORIN Rimedio
	Over-the-counter drugs	- 1	- 3	otc and sales others decreased
	Skin care business	- 2	0	sales decreased because of concentration of distribution route to mail order system
<b>Operating Income</b>	+ 3	- 4	<ul style="list-style-type: none"> <li>➢gross profit</li> <li>•increase year on year, effect of sales increase</li> <li>•decreased against original forecast , influence of downward sales and rise of cost of sales ratio(mainly new product and exchange rate)</li> <li>➢SG&amp;A Expenses (excluding R&amp;D Expenses)</li> <li>•Increase year on year(R&amp;D,SG&amp;A)</li> <li>•Fall below original forecast (reduced R&amp;D expense ¥ - 0.3bln)</li> </ul>	

**Kyorin group will try to improve new records for sales and earnings**

[for reference]

- Cost of sales ratio : a slight increase year on year
- SG&A ratio(include R&D expense) : remain mostly level year on year
- R&D expense ¥11.8bln(+ 0.7bln)



# Forecast of Mainstay Product Sales and Generic Drugs



(unit : ¥100mil)

	Mar/13	Mar/14 Revised forecast	Change	% Change	Change from original forecast
<b>Kipres</b>	396	<b>403</b>	+ 7	+ 1.8	- 5
<b>Mucodyne</b>	191	<b>188</b>	- 3	- 1.6	+ 1
<b>Pentasa</b>	176	<b>185</b>	+ 9	+ 5.1	- 1
<b>Uritos</b>	75	<b>80</b>	+ 5	+ 7.2	- 4
<b>Gatifloxacin (Over seas)</b>	16	<b>18</b>	+ 2	+ 11.8	+ 2
<b>Generic Drugs</b>	101	<b>114</b>	+ 13	+ 13.3	+ 3

# Shareholder Returns

## Basic Policy

The Company seeks to enhance its management base by balancing investments for growth and business continuity with shareholder returns. To this end, the Company aims for a consolidated payout ratio to shareholders of 30%.

### Net Income

	FY12	FY13 (original forecast)	FY13 (revised forecast)
<b>Net Income</b>	¥12.4bln	¥12.7bln	¥12.4bln

### Dividends

	FY12	FY13 (original forecast)	FY13 (revised forecast)
<b>Dividend per share (Yen)</b>	¥50.00 (interim ¥10.00)	¥52.00 (interim ¥10.00)	¥52.00 (interim ¥10.00)
<b>Consolidated payout ratio(%)</b>	30.1%	30.6%	31.2%

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.