

# **Interim Term Financial Results Ended September 2011**

**November 9,2011  
KYORIN Holdings, Inc.  
President Masahiro Yamashita**



- **Outline of Consolidated Financial Results  
for the Interim Term Ended September 2011**
- **Trends of mainstay products (domestic ・ overseas)  
and Status of generic drugs**
- **Consolidated Financial Results Forecast for the Year  
Ending March 31, 2012 and Dividends**
- **Status of development pipeline**
  - ◇ Progress in first half of fiscal 2011 and initiatives in second half of fiscal 2011

**Outline of Consolidated Financial Results  
for the Interim Term Ended September 2011**

# Outline of Consolidated Financial Results for the Interim Term Ended September 2011



( Units: ¥ billion )

	Sep/10 (Actual)	Sep/11 (Actual)	Change Sep/10 vs Sep/11	Change %	Change original forecast vs Sep/11
Net Sales	46.7	46.4	△0.3	△0.7%	△2.8
Operating Income	4.2	4.9	+0.7	+16.7%	△1.2
Ordinary Income	4.5	5.3	+0.8	+15.7%	△1.1
Net Income	3.0	3.4	+0.4	+13.4%	△0.6

# Increase/Decrease of Segment Sales (Consolidated)

( Units: ¥ billion )

			Sep/10 (Actual)	Sep/11 (Actual)	Change Sep/10 vs Sep/11	Change %	Change original forecast vs Sep/11
<b>Net Sales (total)</b>			<b>46.7</b>	<b>46.4</b>	<b>△0.3</b>	<b>△0.7%</b>	<b>△2.8</b>
			<b>45.4</b>	<b>45.2</b>	<b>△0.2</b>	<b>△0.5%</b>	<b>△2.6</b>
<b>Ethical drugs business</b>	<b>Sales of new ethical drugs</b>		<b>39.2</b>	<b>39.1</b>	<b>△0.1</b>	<b>△0.3%</b>	<b>△2.1</b>
		<b>Japan</b>	<b>37.7</b>	<b>38.1</b>	<b>+0.4</b>	<b>+1.1%</b>	<b>△1.8</b>
		<b>Overseas</b>	<b>1.5</b>	<b>1.0</b>	<b>△0.5</b>	<b>△35.4%</b>	<b>△0.3</b>
	<b>Generic drugs</b>		<b>4.1</b>	<b>4.1</b>	<b>△0.0</b>	<b>△0.4%</b>	<b>△0.5</b>
	<b>Over-the-counter drugs</b>		<b>2.0</b>	<b>2.0</b>	<b>△0.0</b>	<b>△4.4%</b>	<b>△0.0</b>
<b>Healthcare Business</b>			<b>1.3</b>	<b>1.2</b>	<b>△0.1</b>	<b>△7.6%</b>	<b>△0.2</b>

## 《 Breakdown of Sales 》

	Change Sep/10 vs Sep/11	Change original forecast vs Sep/11	Explanation of Variances
<b>new ethical drugs (Japan)</b>	<b>+0.4</b>	<b>△1.8</b>	Ethical drug sales in Japan declined forecast, reflecting an increase in distribution inventory at the end of the fiscal year ended March in association with the Great East Japan Earthquake.
<b>new ethical drugs (Overseas)</b>	<b>△0.5</b>	<b>△0.3</b>	Gatifloxacin's sales declined original forecast.
<b>Generic drugs</b>	<b>△0.0</b>	<b>△0.5</b>	Decrease sales of strategic products and supplementary products.

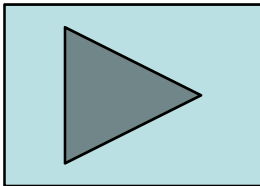
# Breakdown of Gain and Loss

( Units: ¥ billion )

	Sep/10 (Actual)	Sep/11 (Actual)	Change Sep/10 vs Sep/11	Change %	Change original forecast vs Sep/11
<b>Net Sales</b>	<b>46.7</b>	<b>46.4</b>	<b>△0.3</b>	<b>△0.7%</b>	<b>△2.8</b>
<b>Cost of Sales</b>	<b>17.1</b>	<b>16.6</b>	<b>△0.5</b>	<b>△2.8%</b>	<b>—</b>
<b>SG&amp;A</b>	<b>25.4</b>	<b>24.9</b>	<b>△0.5</b>	<b>△2.2%</b>	<b>—</b>
<b>R&amp;D Expenses</b>	<b>6.9</b>	<b>6.1</b>	<b>△0.8</b>	<b>△11.7%</b>	<b>△0.4</b>
<b>SG&amp;A Expenses (excluding R&amp;D Expenses)</b>	<b>18.5</b>	<b>18.8</b>	<b>+0.3</b>	<b>+1.4%</b>	<b>—</b>
<b>Operating Income</b>	<b>4.2</b>	<b>4.9</b>	<b>+0.7</b>	<b>+16.7%</b>	<b>△1.2</b>
<b>Ordinary Income</b>	<b>4.5</b>	<b>5.3</b>	<b>+0.8</b>	<b>+15.7%</b>	<b>△1.1</b>
<b>Net Income</b>	<b>3.0</b>	<b>3.4</b>	<b>+0.4</b>	<b>+13.4%</b>	<b>△0.6</b>

《Sep/10 vs Sep/11》

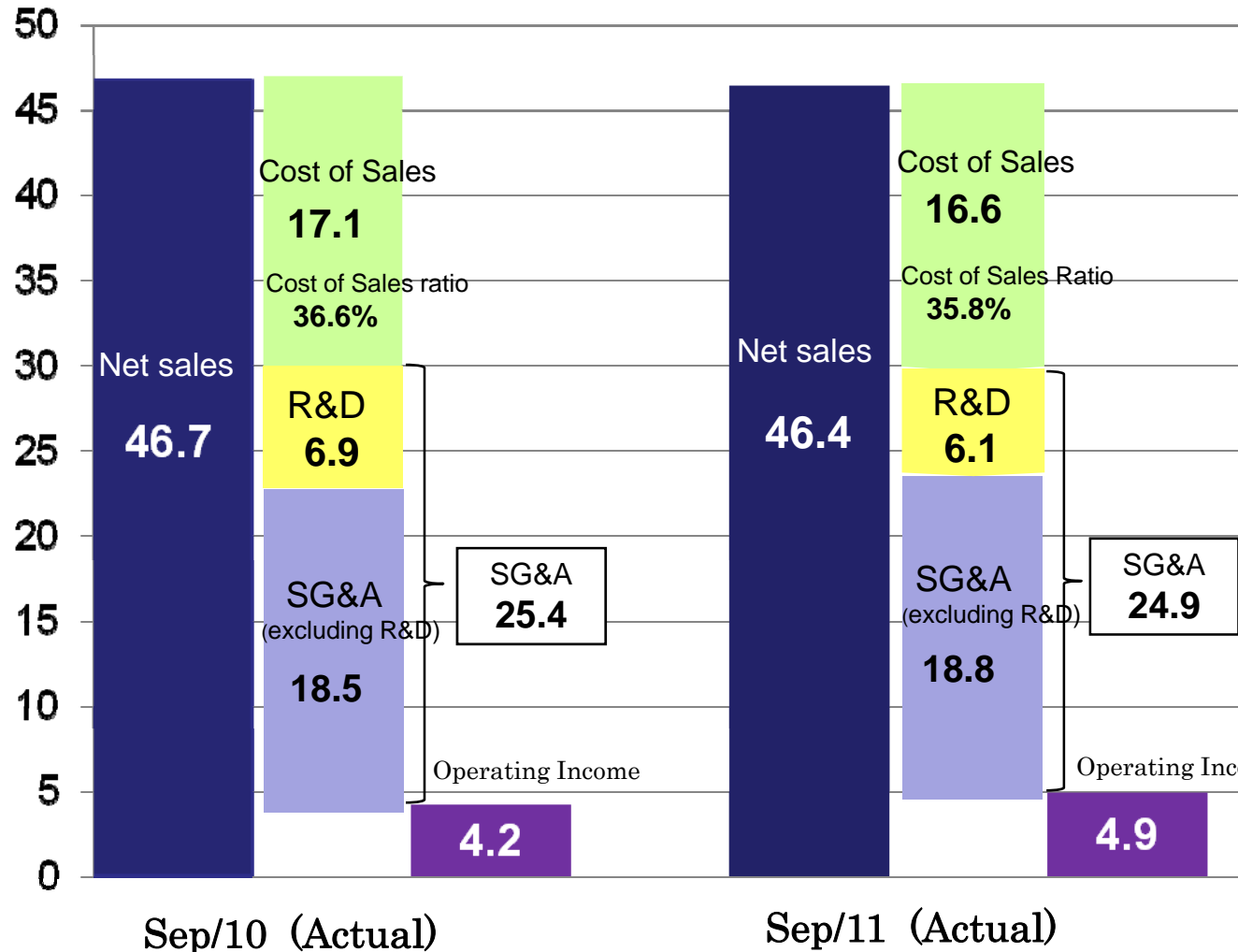
《original forecast vs Sep/11》



	Change original forecast vs Sep/11	Explanation of Variances
<b>Net Sales</b>	<b>△2.8</b>	new ethical drugs(Japan)△1.8、new ethical drugs (Overseas)△0.3、 Generic drugs△0.5
<b>Operating Income</b>	<b>△1.2</b>	Save R&D Expense and SG&A Expense to avoid the decrease of Operating Income. (R&D Expense : vs original forecast △0.4)

# Highlights of Business Performance

( Units: ¥ billion )



## Highlight ①

◇ Net Sales decreased ¥0.3 billion year on year.

(reflecting an increase in distribution inventory at the end of the fiscal year ended March in association with the Great East Japan Earthquake. )

## Highlight ②

◇ Cost of Sales declined ¥0.5 bln. (The Cost of Sales Ratio fell 0.8 points.)

- Increased sales of in-house products with lower Cost of Sales
- a rise in the factory operation ratio
- a decrease of manufacturing cost

◇ Gross profit increased (up ¥0.2bln year on year).

## Highlight ③

◇ SG&A Expenses dropped ¥0.5bln year on year. (Of SG&A Expenses, R&D Expenses decreased ¥0.8bln.)

(Expenses associated with the completion of the R&D of KRP-108 Ph2b were posted in the previous year )

◆ Operating Income rose ¥0.7 bln year on year.



# Increase/Decrease of Mainstay Product Sales

( Units: ¥ billion )

	Sep/10 (Actual)	Sep/11 (Actual)	Change Sep/10 vs Sep/11	Change %	Change original forecast vs Sep/11
<b>Kipres</b>	<b>14.1</b>	<b>15.7</b>	<b>+1.6</b>	<b>+11.5%</b>	<b>△0.5</b>
<b>Mucodyne</b>	<b>9.4</b>	<b>9.1</b>	<b>△0.3</b>	<b>△3.4%</b>	<b>△0.6</b>
<b>Pentasa</b>	<b>9.9</b>	<b>9.1</b>	<b>△0.8</b>	<b>△7.3%</b>	<b>△0.6</b>
<b>Uritos</b>	<b>2.4</b>	<b>2.9</b>	<b>+0.5</b>	<b>+21.4%</b>	<b>△0.1</b>
<b>Gatifloxacin (Over seas)</b>	<b>1.3</b>	<b>0.8</b>	<b>△0.5</b>	<b>△38.4%</b>	<b>△0.3</b>

【 For reference 】 growth rate of sales for medical institution ( calculated based on drug price)

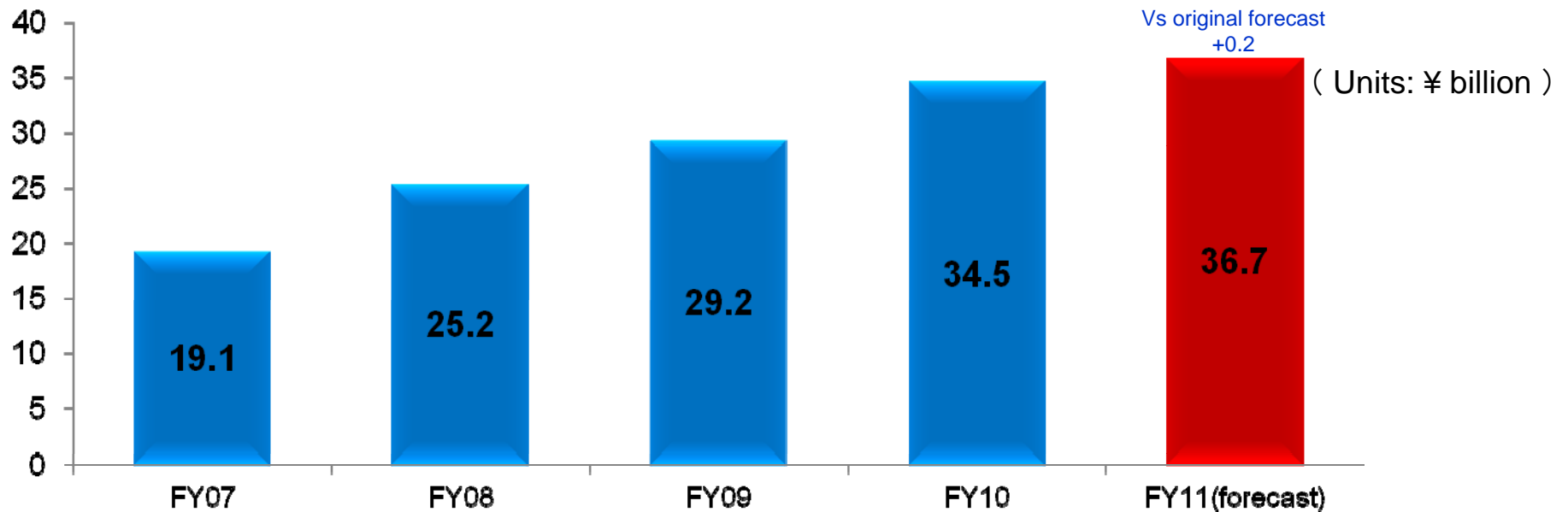
Kipres	+16.8%
Mucodyne	+0.8%
Pentasa	△5.3%
Uritos	+26.5%

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**Trends of mainstay products (domestic · overseas)  
and Status of Generic drugs**

# Kipres 【Bronchial asthma and allergic rhinitis treatment】



## ■ Status in Fiscal 2011

### ● Establish position as base drug for treatment of allergic rhinitis

- Allergic rhinitis: raise awareness as a chronic inflammatory condition
- Build evidence

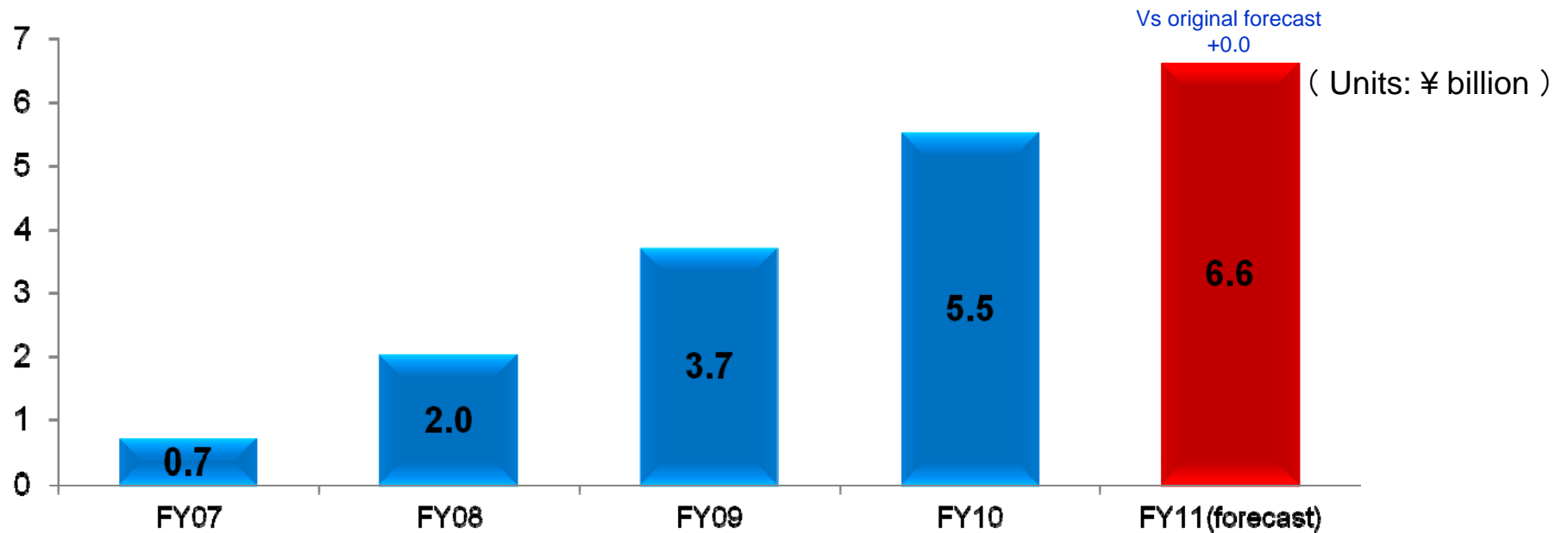
### ● Further promote prescription for adult and childhood asthma

### ● Increased market share for LT antagonists

31.3% (March 2011 MAT) ⇒ 32.2% (September 2011 MAT)

(Source: IMS JAPAN K.K., JPM, March 2011/September 2011 MAT. Unauthorized copying prohibited)

# Uritos 【Overactive bladder】



## ■ Status in Fiscal 2011

- **Tap into latent market.**

OAB market: ¥60.0 billion (MAT Mar 11) ⇒ ¥62.0 billion (MAT Sep 11)

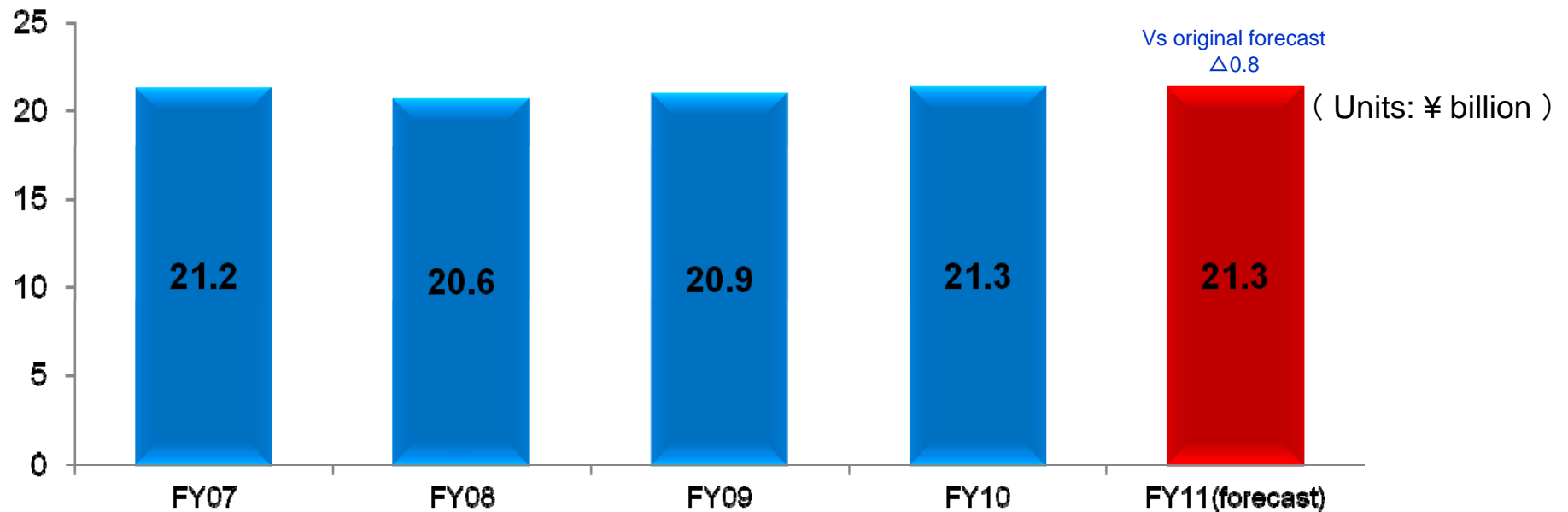
- **Expand Market penetration of OD (orally disintegrating) tablet and promote as first-choice OAB treatment (Uritos OD tablet was Launched Apr 2011).**

- **Expand Uritos's share of OAB market.**

	MAT Mar 11		MAT Sep 11
・Uritos	9.3%	⇒	10.1%
・Imidafenacin	19.3%	⇒	20.4%

(Source: IMS JAPAN K.K., JPM, March 2011/September 2011 MAT. Unauthorized copying prohibited)

# Mucodyne 【 Mucoregulating drug】



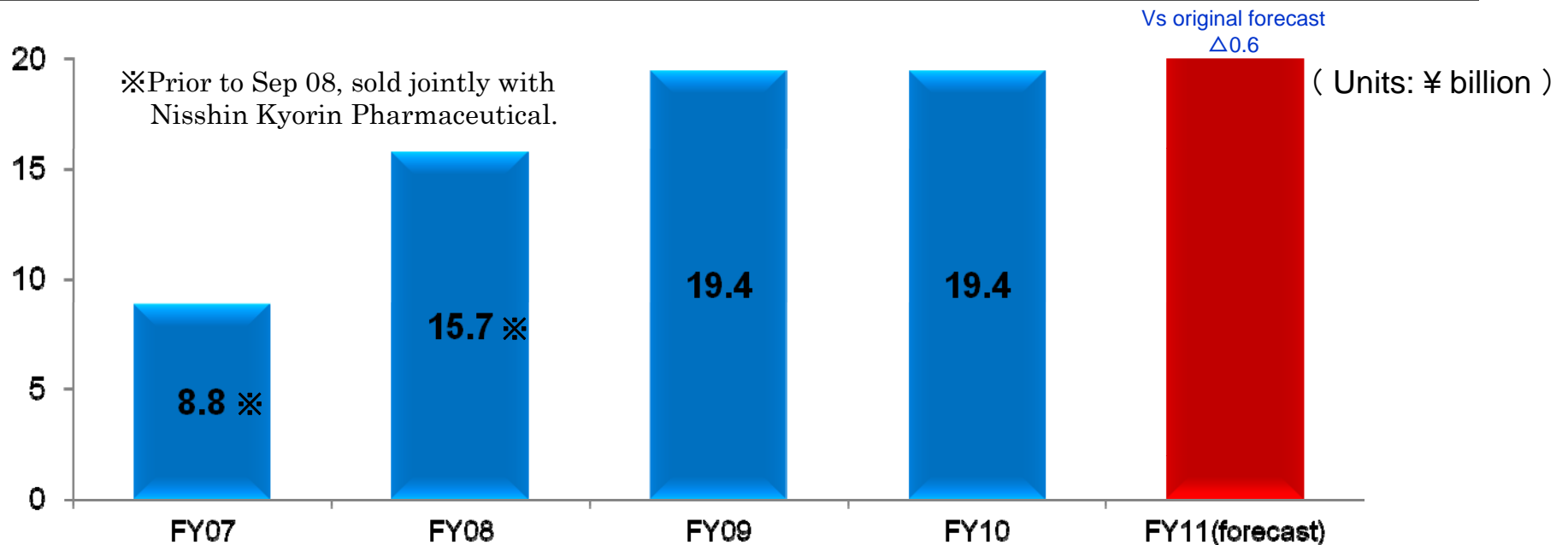
## ■ Status in Fiscal 2011

- Maximize uptake and prescriptions of new formulation 「DS50%」 (Launched May 2010).
- Increase prescriptions for chronic conditions based on EBM. chronic respiratory disorder , and chronic sinusitis
- Expand Mucodyne 's share of market.

47.9% ( MAT Mar 11 ) ⇒ 48.3% ( MAT Sep 11 )

(Source: IMS JAPAN K.K., JPM, March 2011/September 2011 MAT. Unauthorized copying prohibited)

# Pentasa 【 Ulcerative colitis and Crohn's disease treatment 】

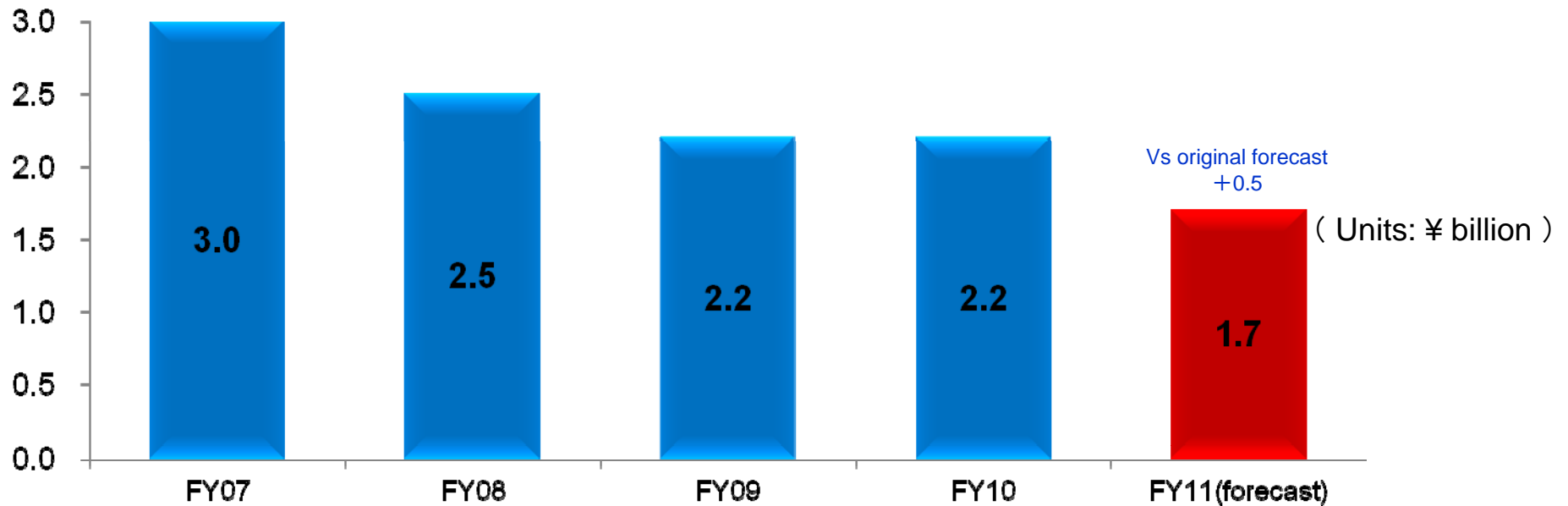


## ■ Status in Fiscal 2011

- **Establish basic prescription for ulcerative colitis.**
- **Expand market for mesalazine formulations and market share**
  - Growth of around 13% for mesalazine formulations (number of patient increased around 7%)  
¥26.5billion ( MAT Sep 10 ) ⇒ ¥30.0billion ( MAT Sep 11 )
  - Pentasa's share  
80.2%( MAT Sep 10 ) ⇒ 68.2%( MAT Sep 11 )

(Source: IMS JAPAN K.K., JPM, September 2010/September 2011 MAT. Unauthorized copying prohibited)
- **Development of new dosage and dose regimen (once-a-day administration) and new drug formulation (suppositories).**

# Gatifloxacin 【Anti-bacterial eye drops (Overseas)】



## ■ Status in Fiscal 2011

### ● Promote sales of high concentration formulations of Gatifloxacin (by Allergan).

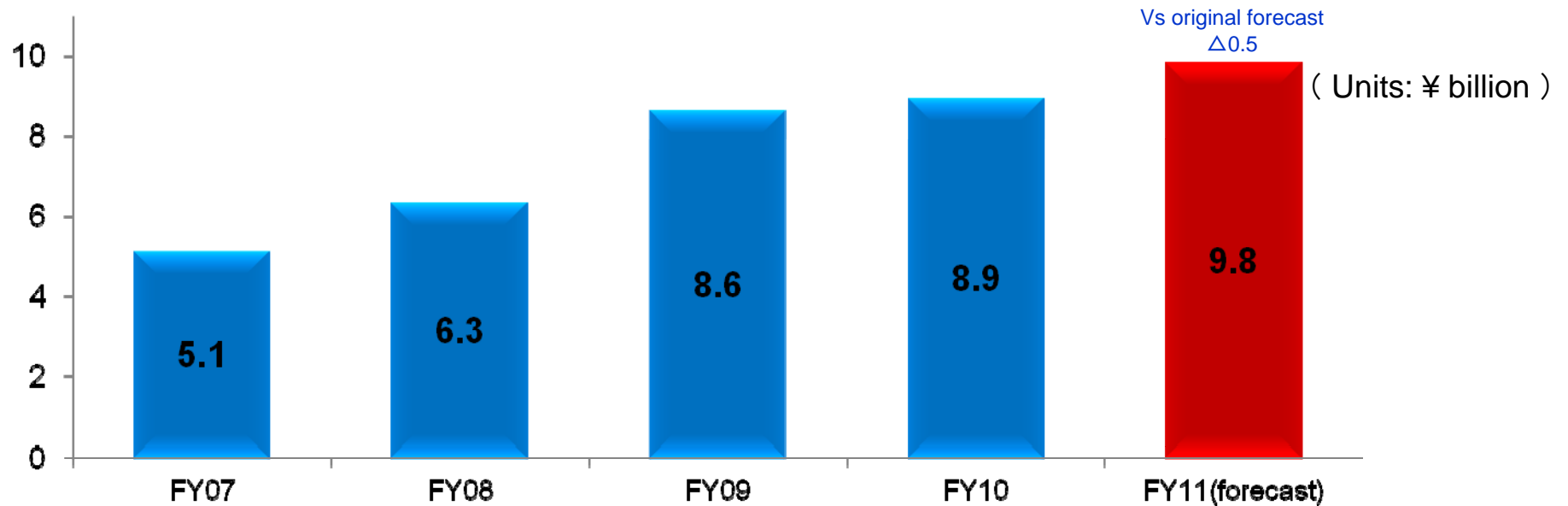
- Zymaxid: 0.5% launched by Allergan in June 2010
- Zymar: 0.3% discontinued in March 2011

#### 【For reference】

Sales of Zymar and Zymaxid : first half of 2010 \$50MM ⇒ first half of 2011 \$49MM

### ● There's no generics sales at the present time of Oct 31 2011 (U.S.).

# Status of Generic Drugs



## ■ Status in Fiscal 2011

- **Expand sales via wholesaler sales route.**
- **Increase sales of supplementary products.**
  - Increase sales Edaravoneof in hospital.
  - Plan to launch 5 supplementary ingredients and 10 supplementary products (November).
- **Promote domestic and overseas alliances**
  - Expand of commissioned manufacturing
  - Promote of Co-development

**Consolidated Financial Results Forecast  
for the Year Ending March 31, 2012  
and Dividends**



# Consolidated Financial Results Forecast for the Year Ending March 31, 2012

( Units: ¥ billion )		Mar/11 (Actual)	Mar/12 original forecast	Mar/12 Revised forecast	Change VS original forecast	Change VS Mar/11 actual	Change %
Net Sales (total)		<b>104.1</b>	<b>106.5</b>	<b>105.1</b>	<b>△1.4</b>	<b>+1.0</b>	<b>+1.0%</b>
	Ethical drugs business	<b>101.3</b>	<b>103.5</b>	<b>102.2</b>	<b>△1.3</b>	<b>+0.9</b>	<b>+1.0%</b>
	Healthcare Business	<b>2.8</b>	<b>3.0</b>	<b>2.8</b>	<b>△0.2</b>	<b>+0.0</b>	<b>+2.7%</b>
Operating Income		<b>16.4</b>	<b>16.6</b>	<b>14.9</b>	<b>△1.7</b>	<b>△1.5</b>	<b>△9.4%</b>
Ordinary Income		<b>17.1</b>	<b>17.2</b>	<b>15.6</b>	<b>△1.6</b>	<b>△1.5</b>	<b>△8.8%</b>
Net Income		<b>10.9</b>	<b>10.9</b>	<b>10.1</b>	<b>△0.8</b>	<b>△0.8</b>	<b>△7.6%</b>

《Vs Mar/12 original forecast》

		Change VS original forecast	Explanation of Variances
Net Sales (total)		<b>△1.4</b>	
	new ethical drugs (Japan)	<b>△0.9</b>	revised sales of Mainstay Product
	new ethical drugs (Overseas)	<b>+0.4</b>	revised sales of Gatifloxacin upward
	Generic drugs	<b>△0.5</b>	revised sales of strategic products and supplementary products downward
	etc.	<b>△0.4</b>	Revised sales of Over-the-counter drugs and Dr.Program downward.
Operating Income		<b>△1.7</b>	R&D expenses rose ¥ 0.8 bln. (Advancements in development pipeline)(original forecast: ¥13.4bln, revised forecast: ¥14.2bln)

《Vs Mar/11 actual》

**【 For reference 】**

- Cost of Sales Ratio: down 1 percentage points
- R&D Expenses rose ¥ 1.7 bln  
(SG&A Expenses Ratio: up 2 percentage points)

# Forecast of Mainstay Product Sales and Generic Drugs

( Units: ¥ billion )

	Mar/11 (Actual)	Mar/12 original forecast	Mar/12 Revised forecast	Change VS original forecast	Change VS Mar/11 actual	Change %
<b>Kipres</b>	<b>34.5</b>	<b>36.5</b>	<b>36.7</b>	<b>+0.2</b>	<b>+2.2</b>	<b>+6.5%</b>
<b>Mucodyne</b>	<b>21.3</b>	<b>22.1</b>	<b>21.3</b>	<b>△0.8</b>	<b>+0.0</b>	<b>+0.5%</b>
<b>Pentasa</b>	<b>19.4</b>	<b>19.2</b>	<b>18.6</b>	<b>△0.6</b>	<b>△0.8</b>	<b>△4.0%</b>
<b>Uritos</b>	<b>5.5</b>	<b>6.6</b>	<b>6.6</b>	<b>△0.0</b>	<b>+1.1</b>	<b>+20.2%</b>
<b>Gatifloxacin (Over seas)</b>	<b>2.2</b>	<b>1.2</b>	<b>1.7</b>	<b>+0.5</b>	<b>△0.5</b>	<b>△22.7%</b>
<b>Generic Drugs</b>	<b>8.9</b>	<b>10.3</b>	<b>9.8</b>	<b>△0.5</b>	<b>+0.9</b>	<b>+10.3%</b>

# 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

	<b>FY2011 (Forecast)</b>
Net Income (Billions of yen)	10.9

<b>FY2012 (Original forecast)</b>	<b>FY2012 (Revised forecast)</b>
10.9	<b>10.1</b>

## Dividends

	<b>FY2011 (Forecast)</b>
Dividend per share (Yen)	45.00
Consolidated payout ratio(%)	30.8

<b>FY2012 (Original forecast)</b>	<b>FY2012 (Revised forecast)</b>
45.00	<b>45.00</b>
30.9	<b>33.3</b>

- 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.