

Interim Term Financial Results Ended September 2014

**November 5 , 2014
KYORIN Holdings, Inc.
President Masahiro Yamashita**



- Outline of Consolidated Financial Results for the Interim Term Ended September 2014
- Trends of mainstay products and Status of generic drugs
- Status of development pipeline
- Consolidated Financial Results Forecast for the Year Ending March 31 2015 and Dividends

**Outline of Consolidated Financial Results
for the Interim Term Ended September 2014**

Outline of Consolidated Financial Results for the Interim Term Ended September 2014



(unit : ¥billion)

| | Sep/13 | Sep/14 | Change (actual) | % Y/Y | Change (forecast) |
|------------------|--------|-------------|--------------------|-------|----------------------|
| Net Sales | 50.9 | 51.1 | +0.2 | +0.5 | -0.2 |
| Operating Income | 6.2 | 4.6 | -1.6 | -26.2 | -0.9 |
| Ordinary Income | 6.5 | 4.9 | -1.6 | -25.0 | -0.8 |
| Net Income | 4.4 | 3.5 | -0.9 | -20.5 | -0.4 |

Segment Sales (Consolidated)

(unit : ¥billion)

| | | Sep/13 | Sep/14 | Change (actual) | % Y/Y | Change (forecast) | |
|-------------------------------|-----------------------------------|-----------------|-------------|--------------------|--------|----------------------|------|
| Net Sales | | 50.9 | 51.1 | +0.2 | +0.5 | -0.2 | |
| Ethical drugs business | | 50.0 | 50.5 | +0.5 | +1.0 | -0.1 | |
| | Sales of new ethical drugs | | 42.9 | 40.8 | -2.1 | -4.9 | -1.3 |
| | | Japan | 41.7 | 40.4 | -1.3 | -3.1 | -1.3 |
| | | Overseas | 1.2 | 0.3 | -0.9 | -71.3 | -0.1 |
| | Generic drugs | | 5.2 | 7.8 | +2.6 | +50.3 | +1.4 |
| | Over-the-counter drugs | | 2.0 | 2.0 | 0 | -1.3 | -0.1 |
| Healthcare Business | | 0.8 | 0.6 | -0.2 | - 26.8 | -0.1 | |

| | change (y/y) | change (forecast) | Explanation of Variances |
|--------------------------|-----------------|----------------------|---|
| new ethical drugs | -2.1 | -1.3 | <ul style="list-style-type: none"> ➢ Drug price revisions (in the 6% range for KYORIN Pharmaceutical) ,Mucodyne and Pentasa etc. decreased year on year ➢ Increase of new product Fultiform (year on year+¥0.9、 compared to forecast +¥0.1) ➢ sales of Gatifloxacin decreased effect of generic product was launched in USA (oct/13) (sales of Allergan : FY13 first half \$35MM→FY14 first half \$14MM) |
| Generic drugs | +2.6 | +1.4 | <ul style="list-style-type: none"> ➢ Contract manufacturing's sales and Health insurance pharmacy market's sales increased |

Breakdown of Gain and Loss

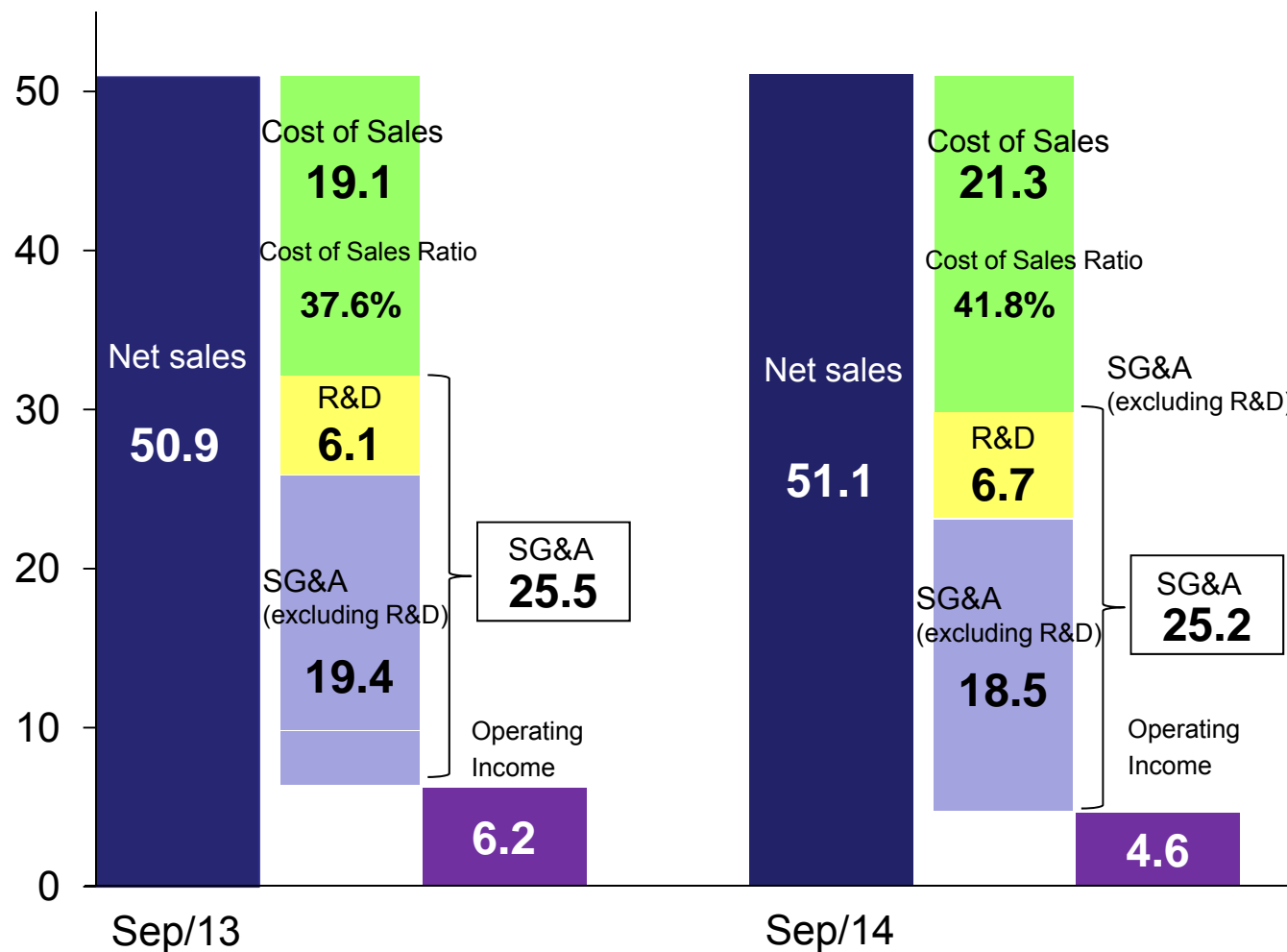
(unit : ¥billion)

| | Sep/13 | Sep/14 | Change (actual) | % Y/Y | Change (forecast) |
|------------------|--------|--------|--------------------|-------|----------------------|
| Net Sales | 50.9 | 51.1 | +0.2 | +0.5 | -0.2 |
| Cost of Sales | 19.1 | 21.3 | +2.2 | +11.7 | - |
| SG&A | 25.5 | 25.2 | -0.3 | -1.4 | - |
| R&D expenses | 6.1 | 6.7 | +0.6 | +9.1 | +1.0 |
| SG&A expenses | 19.4 | 18.5 | -0.9 | -4.7 | - |
| Operating Income | 6.2 | 4.6 | -1.6 | -26.2 | -0.9 |
| Ordinary Income | 6.5 | 4.9 | -1.6 | -25.0 | -0.8 |
| Net Income | 4.4 | 3.5 | -0.9 | -20.5 | -0.4 |

| | change (y/y) | change (forecast) | Explanation of Variances |
|------------------|-----------------|----------------------|--|
| Operating Income | -1.6 | -0.9 | <ul style="list-style-type: none"> ➢ gross profit : decreased ¥2.0bln (cost of sales ratio increased 4.2% , cost of sales increased ¥2.2bln) <ul style="list-style-type: none"> • Drug price revisions (in the 6%range for KYORIN Pharmaceutical) , sales of generic drugs increased , sales of ethical drug overseas decreased , Mucodyne and Pentasa etc. decreased ➢ R&D expense increased ¥0.6bln (up front payment of KRP-114V) ➢ SG&A (exclude R&D) expense decreased ¥0.9bln (decrease of sales costs, labor costs, general expenses) |

Highlights of Business Performance

(Units: ¥billion)



➤ **Net Sales increased ¥0.2billion year on year.**

- decrease of new ethical drugs sales.
- increase of generic drugs sales.

➤ **Cost of Sales increased ¥2.2 billion. (Cost of sales ratio increased 4.2%)**

- Drug price revisions
- Sales of generic drugs increased
- Sales of ethical drug overseas decreased

■ **Gross Profit decreased ¥2.0billion year on year**

➤ **SG&A expenses decreased ¥0.3billion year on year.**

- R&D expenses increased ¥0.6billion (up front payment)
- SG&A(excluding R&D) decreased ¥0.9billion

■ **Operating Income decreased ¥1.6billion year on year.**

Mainstay Product Sales

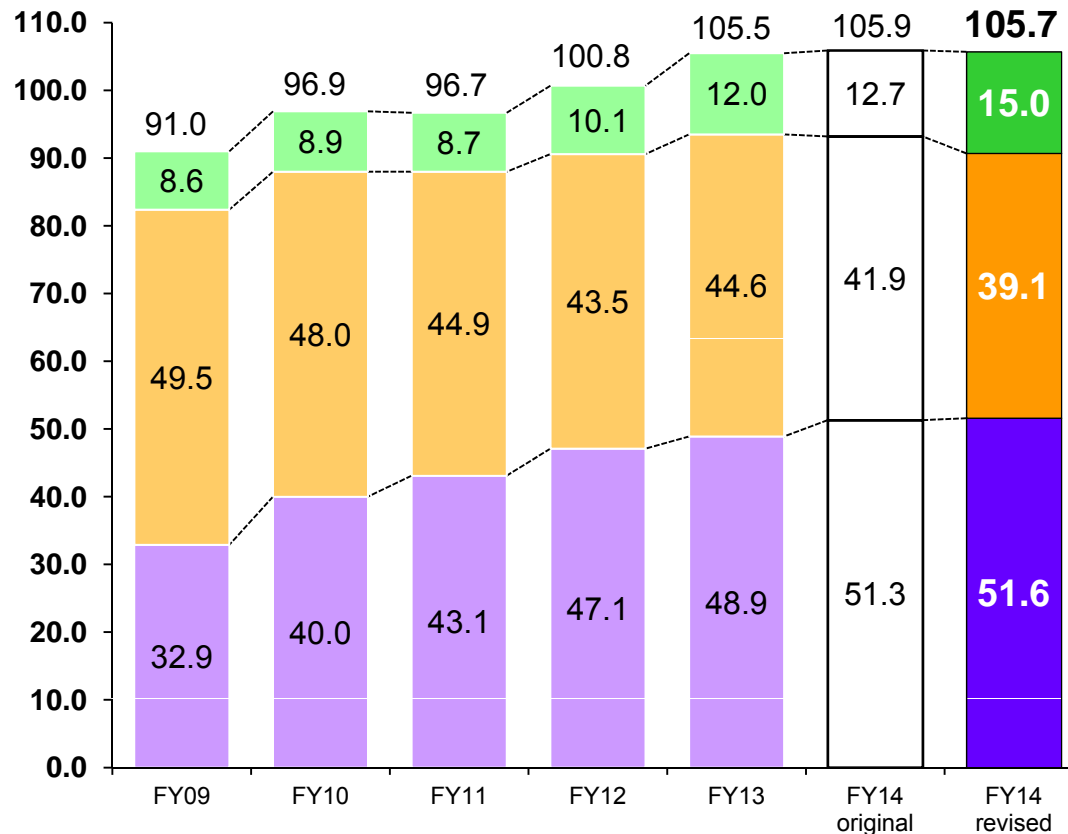
(unit : ¥billion)

| | Sep/13 | Sep/14 | Change (actual) | % Y/Y | Change (forecast) |
|------------------|--------|-------------|--------------------|-------|----------------------|
| Kipres | 17.1 | 17.4 | +0.3 | +2.0 | +0.1 |
| Mucodyne | 8.2 | 6.2 | -2.0 | -24.8 | -1.0 |
| Pentasa | 9.4 | 8.6 | -0.8 | -8.1 | -0.3 |
| Uritos | 3.7 | 3.4 | -0.3 | -9.9 | -0.3 |
| Flutiform | — | 0.9 | +0.9 | — | +0.1 |

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

Ethical Drug Business

(unit : ¥billion)



Pharma Complex Model (PC Model)

New drugs group

- Maximize uptake of **Kipres, Uritos, Flutiform**
- Enhance the Development Pipeline (**KRP-AB1102**)

Original products group

- Use LCM to raise value of focus products (**Mucodyne, Pentasa**) and extend lifecycle

Generic drugs group

- Promote domestic and overseas alliances to enhance product lineup and lower costs
- Leverage stronger ties within the KYORIN Group to promote a more distinctive generics business
- promotion of collaborative development

LCM: Life Cycle Management

New drugs group Kipres, Uritos, Flutiform

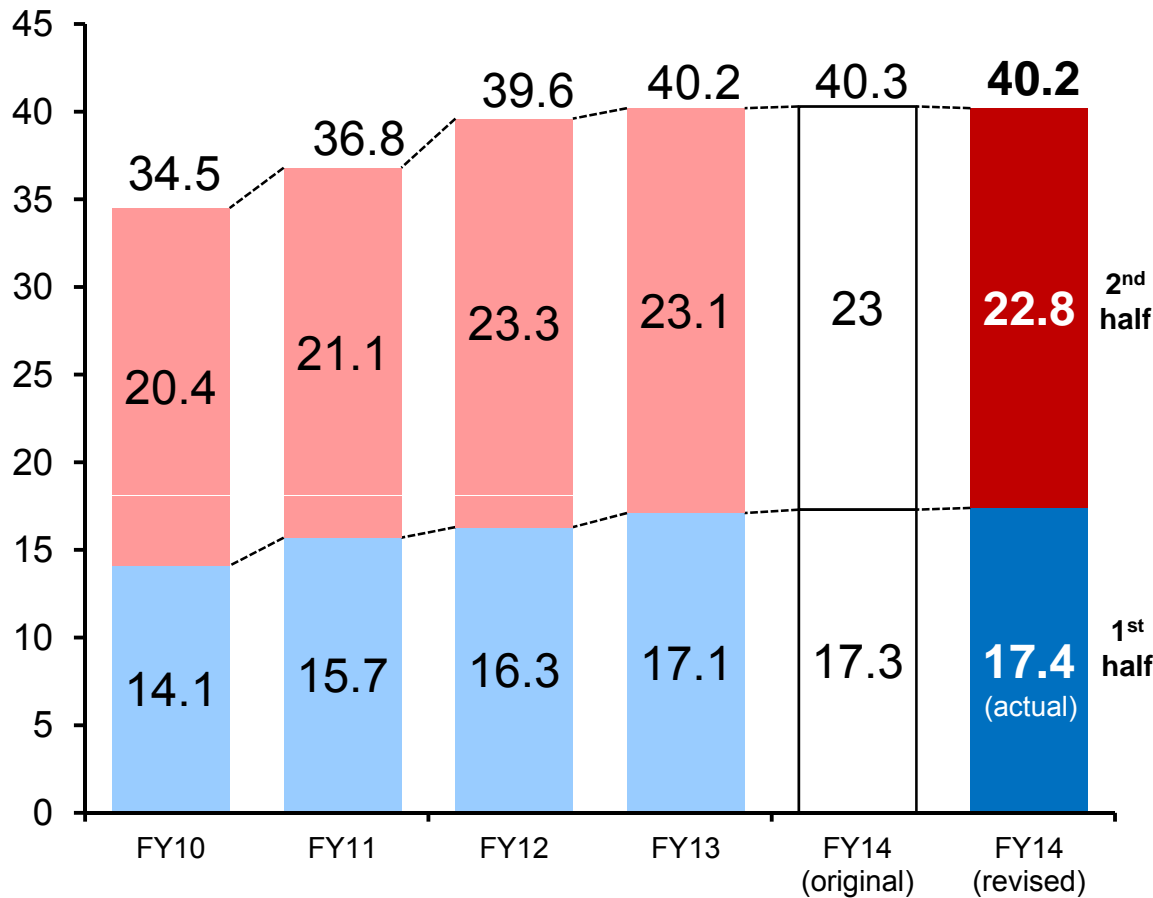
Original products group Mucodyne, Pentasa

Generic drugs group

■ New drugs group

Kipres 【Bronchial asthma and allergic rhinitis treatment】

(unit : ¥billion)



➤ **Status in first half 2014**

■ **LT antagonists market : 2% reduction**

¥57.5bln (FY13 first half) ⇒ ¥56.2bln (FY14 first half) ※1

■ **share of Kipres sales**

35.7% (FY13 first half) ⇒ 37.2% (FY14 first half) ※2

➤ **effort for FY2014**

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

■ **Further promote prescription**

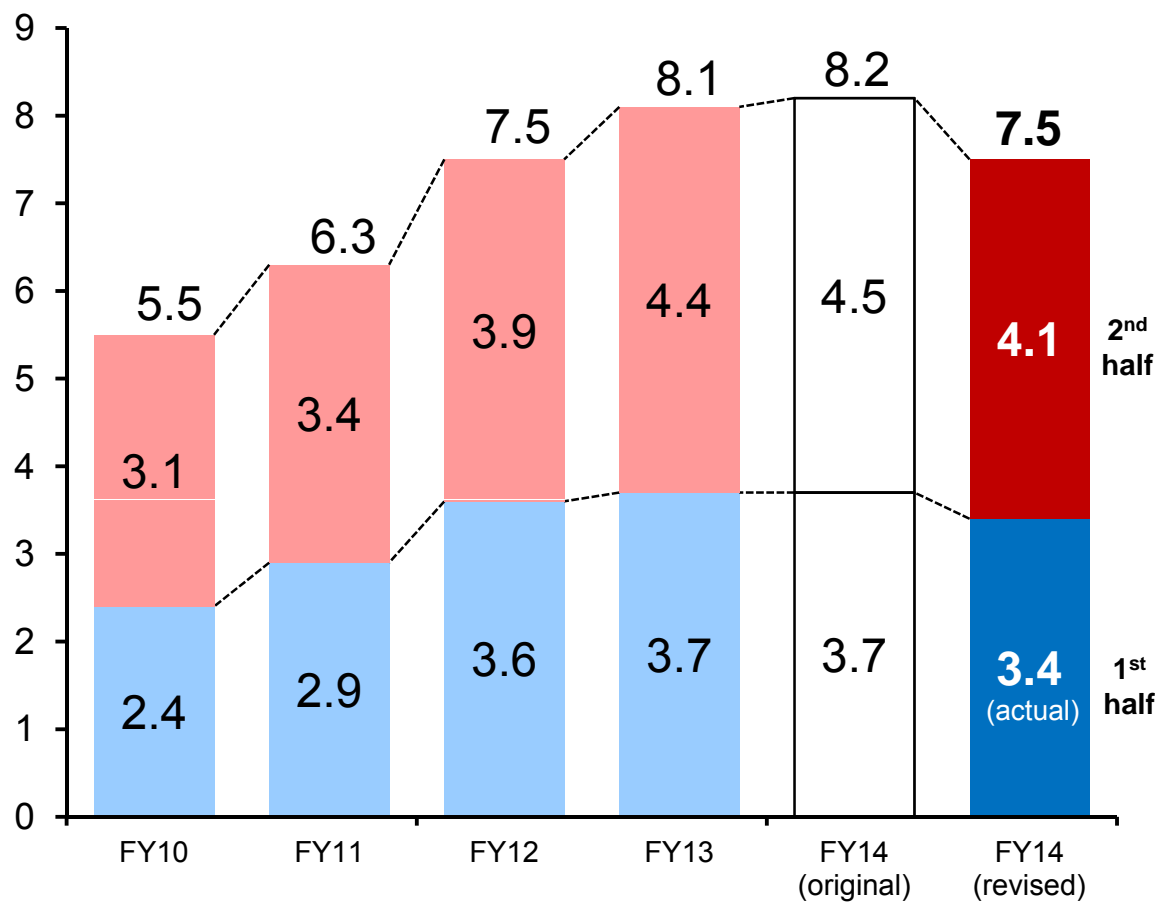
• **price revision rate ▲7.4%**

※1,2 (Source: Copyright 2014 IMS JAPAN IMS –JPM.Unauthorized copying prohibited)

■ New drugs group

Uritos 【Overactive bladder】

(unit : ¥billion)



➤ Status in first half 2014

■ OAB market : expand 3%

¥36.6bln (FY13 first half) ⇒ ¥37.8bln (FY14 first half) ※1

■ share of Uritos sales

11.0% (FY13 first half) ⇒ 10.3% (FY14 first half) ※2

➤ effort for FY2014

■ Uncovering potential markets

FY14 : potential patient 9.2million people / consultation rate 30%

■ Pervading usability

prescriptions based on EBM (OAB patient with BPH ※3)

■ price revision rate ▲0.4%

※1,2 (Source : Copyright 2014 IMS JAPAN IMS -JPM. Unauthorized copying prohibited)

※3 benign prostatic hypertrophy

■ New drugs group

Flutiform 【Anti-asthmatic】

➤ **Status in first half 2014**

FY2014 first half sales: **¥0.9bln** (original + ¥0.1bln)

| | <i>Flutiform 50 Aerosol - 56 inhalations Flutiform 125 Aerosol - 56 inhalations</i> | <i>Flutiform 50 Aerosol - 120 inhalations Flutiform 125 Aerosol - 120 inhalations</i> |
|-----------------|---|---|
| approval | September 2013 | September 2013 |
| launch | November 2013 | December 2014 (scheduled date) |

➤ **effort for FY2014**

FY2014(revised): **¥3.9bln** (FY14 original + ¥1.1bln)

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

• launch of a longer-term prescription formulation(30days,120 inhalations)

• **Further promote prescription to partly controlled asthma patients**

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

• **Promote understanding of the advanced pMDI device**

(The device makes it easy to inhale the drug and allows the drug to reach the central airway and the distal airways.)

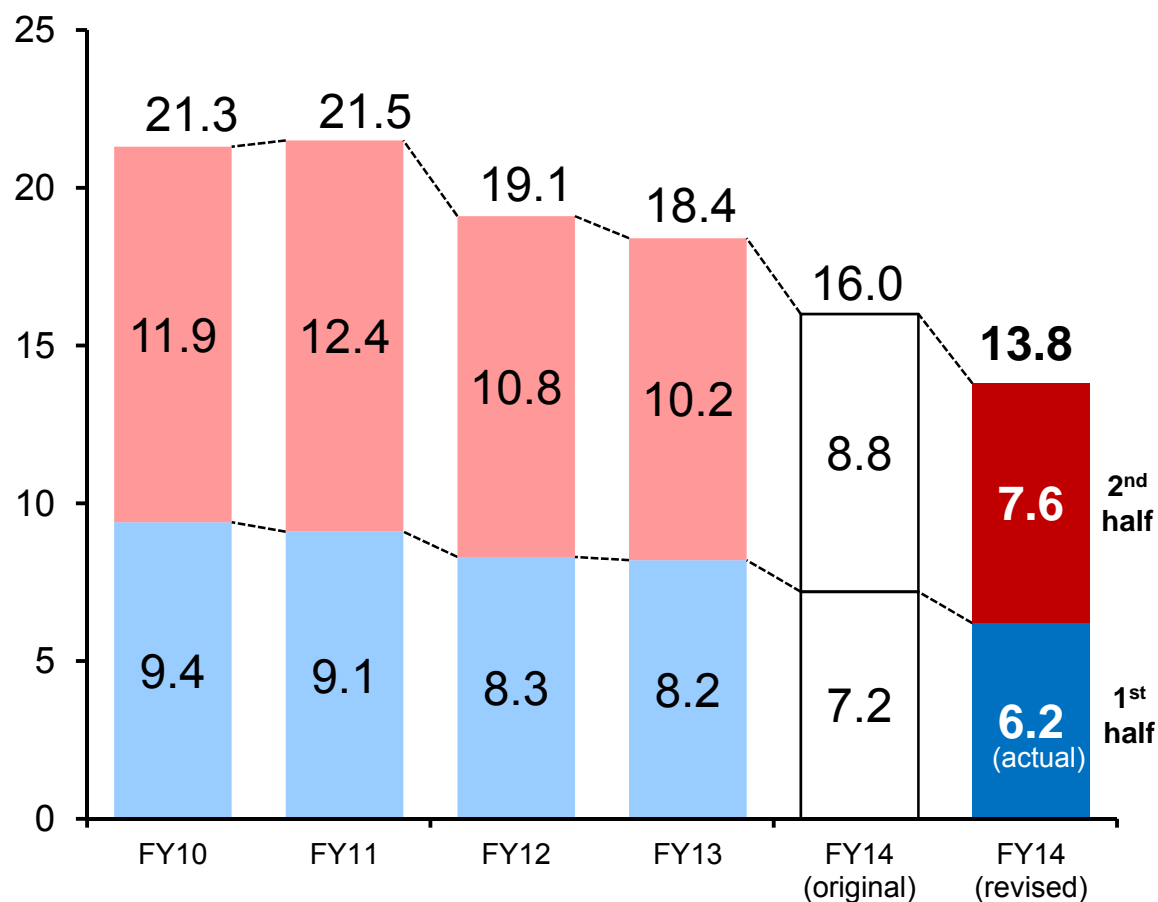
• **appeal advantages of pMDI device**



Original products group

Mucodyne 【 Mucoregulating drug】

(unit : ¥billion)



➤ Status in first half 2014

- **expectorant market: 11% reduction**
¥20.0bln (FY13 first half) ⇒ ¥17.7bln (FY14 first half) ※1
- **share of Mucodyne sales in expectorant market**
45.8% (FY13 first half) ⇒ 41.3% (FY14 first half) ※2
- **share of generic (Carbocisteine)**
6.8% (FY13 first half) ⇒ 10.8% (FY14 first half) ※3

➤ effort for FY2014

- **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,)

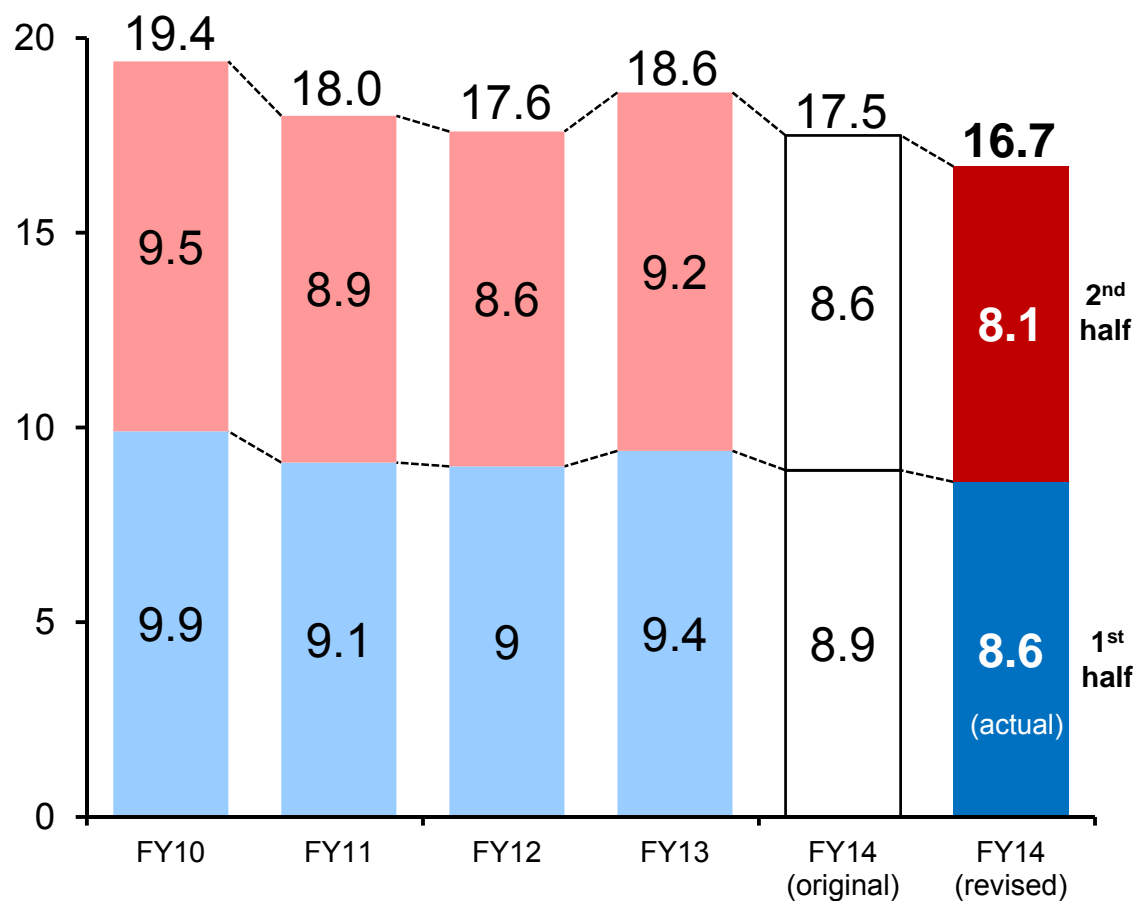
■ price revision rate ▲6.9%

※1, 2, 3 (Source: Copyright 2013 IMS JAPAN IMS -JPM. Unauthorized copying prohibited)

Original products group

Pentasa 【 Ulcerative colitis and Crohn's disease treatment 】

(unit : ¥billion)



➤ Status in first half 2014

■ market (Mesalazine etc.) : expand 2%

¥18.6bln (FY13 first half) ⇒ ¥18.9bln (FY14 first half) ※1

■ share of Pentasa sales

53.9% (FY13 first half) ⇒ 51.6% (FY14 first half) ※2

➤ effort for FY2014

■ prescription for ulcerative colitis active period

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

■ market penetration of suppositories

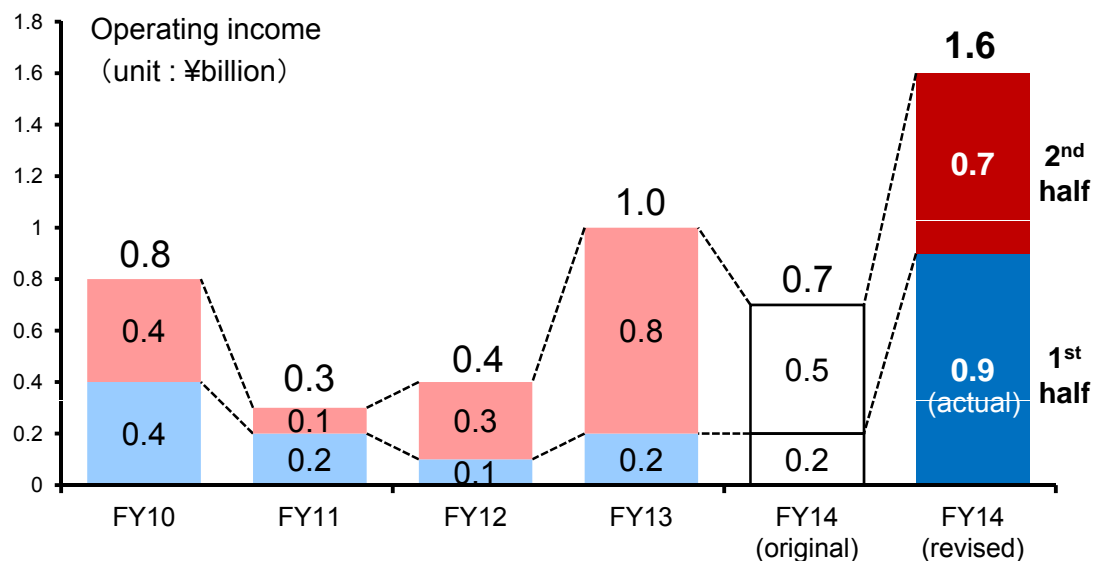
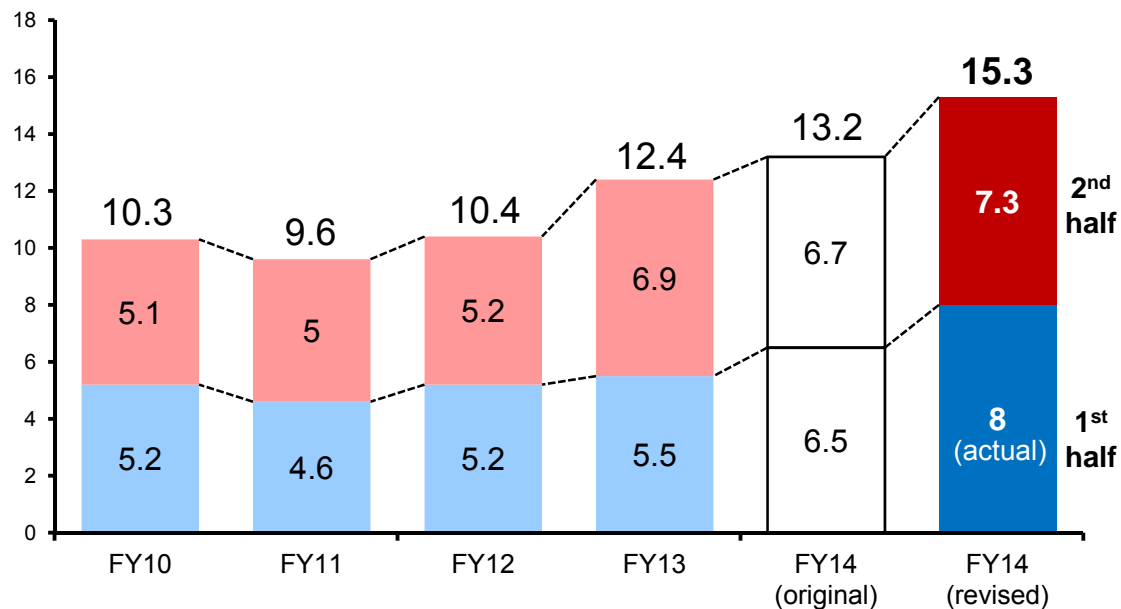
- FY2014 first half sales : ¥0.9bln、FY2014(forecast) ¥1.7bln

• price revision rate ▲7.5%

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Generic drugs group Status of Generic Drugs

Sales (unit : ¥billion)



➤ Status in first half 2014

- Sales : ¥8bln (actual +¥2.5bln, +46.7%)
 - expand of strategic products and supplementary Item launched in FY12, FY13
 - increase of contract manufacturing sales
- Operating income : ¥0.9bln (actual +¥0.7bln, +313.9%)
 - decrease of cost of sales ratio (rise of operation rates)

➤ effort for FY2014

➤ Promotion of Domestic and overseas alliances

- Promote in-house development and contracting work

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

- Sales(revised forecast) : ¥15.3bln (actual +¥2.9bln, +24.4%)
 - expand strategic products : Rabeprazole, Donepezil etc.
 - launch Supplementary Items and Reach Objectives
 - 【coming Supplementary Items Dec/14】**
Levofloxacin, Candesartan
- Operating income(revised forecast) : ¥1.6bln (actual +¥2.9bln, +64.9%)
 - reduce cost of sales
 - promotion of collaborative development (cost reduction by co-developing and promote contracting work)

Status of development pipeline

Drug Development Pipeline: Progress in FY2014

| | Product & development code | Ph I | Ph II | Ph III | application | Approval/ Launch |
|-------------------|----------------------------|------|-------|--------|-------------|---------------------------------|
| Respiratory | Fultiform | | | | | launch Nov/13 56 inhalations |
| | KRP-AB1102 | | | | | launch 120 inhalations |
| | KRP-AB1102F | | | | | approval |
| Urological | KRP-114V | | | | | |
| Otolaryngological | KRP-209 | | | | | |
| Infections | KRP-AM1977X | | | | | |
| | KRP-AM1977Y | | | | | |
| IBD | KRP-203 | | | | | |

progress in FY14 first half
 schedule of FY14 second half

※planning to develop gene-therapy product 「Ad-SGE-REIC」 for the treatment of Malignant Pleural Mesothelioma.
 ※Discontinued development of KIPRES (Chewable, Oral Granules's additional indication for pediatric patient) deleted it from the list of R&D activities.
 ※Discontinued development of KRP-EPA605 deleted it from the list of R&D activities.

COPD treatment agent : KRP-AB1102

■ KRP-AB1102

Action : Long-acting muscarine M3 antagonist (LAMA)

Active ingredient : Acclidinium Bromide

Formulation : Dry Powder Inhaler

Target disease : COPD

Dosage regimen : Inhaled by twice-a-day dosing

Origin : Almirall,S.A(spain)

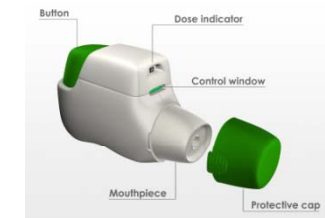
➤ Features

- Fewer systemic side effects
- Twice-daily dosage improves symptoms and respiratory function throughout a day
- Short period reaching maximum effect
- Easy-to-use inhaler device

■ KRP-AB1102F

Fixed dose combination of LAMA and LABA (Long Acting Muscarinic Antagonist)

- LAMA : Acclidinium Bromide
- LABA : Formoterol



- ・「KRP-AB1102」 : aim for approval in FY2014 (application in March 2014)
- ・「KRP-AB1102F」 : aim for early application

Patients : COPD potential patients 5.3million (total number of actual patients in 2011 were 0.2million)^{※1}

COPD treatment agent market (LAMA and fixed dose combination of LAMA and LABA) : about ¥25billion(Sep/2014MAT) ^{※2}

※1 source : Fukuchi,NICE Study 2001, Health, Labour and Welfare Ministry patients survey 2011

※2 source : Copyright 2014 IMS JAPAN IMS –JPM. Unauthorized copying prohibited

Therapeutic agent for overactive bladder : KRP-114V



- Merck has granted to Kyorin an exclusive license to develop , manufacture and commercialize Vibegron in Japan

Action : selective beta 3 adrenergic receptoragonist activity

Active ingredient : Vibegron

Indicaions : The following symptoms associated with overactive bladder: urinary urgency, urinary frequency, and urge urinary in continence.

Dosage regimen : once a day

Status of development : Multi-national Ph2b studies including Japan have been completed by Merck. Kyorin is planning to proceed development in a Phase 3 study in Japan.

Tinnitus treatment agent : KRP-209

■Phase II clinical study (double-blind study)

[Outline of clinical study]

- Subjects : Patients with subjective tinnitus Sample size : Approx. 400 patients
- Endpoints: THI-12* etc. (changes from baseline at each assessment time point)

※ THI : Tinnitus handicap inventory

[Study result]

- Significant improvements from previous values were recognized in all endpoints.
However, no significant difference from the placebo group was observed.
- In the subgroup analysis, multiple significant improvement effects of the actual drug over the placebo were confirmed.

[Future action] We have decided to conduct a POC test again for a specific group of patients.

Gene-Therapy Product「Ad-SGE-REIC※1」

■ Taking on challenges for new drug discovery technology

Target disease : Malignant Pleural Mesothelioma (number of deaths : 1,400 in 2012)

Features : It is expected to have direct effect on primary tumor lesions and indirect effect on metastatic tumor lesions as a gene-therapy drug that simultaneously induces tumor cell-selective apoptosis and the activation of antitumor immunity. Ad-SGE-REIC used in this project uses an adenovirus as a vector.

Development environment :

- ・ Gene-Therapy Product adopted as Next Generation Technology Transfer Program (NexTEP) by JST. ※2
- ・ Creation of the conditional/time limited approval system ※3

Aim for early practical application of the product by bringing into view the “Creation of the conditional/time limited approval system”

※1 discovered by researchers from Okayama University ,as a therapeutic gene

※2 A system through which the Japan Science and Technology Agency (JST) supports large-scale development that enterprises undertake using the seeds based on research results from academia and that may involve development risks to facilitate practical application.

※3 A system under which products for regenerative medicine, including gene-therapy drugs, are specially approved with conditions and for a limited period of time if they are presumed to be effective and their safety is confirmed, even if the number of cases is small.

Reinforce New Drug Business(pipeline)

| Respiratory | Otolaryngological | Urological | IBD |
|---|--|--|------------------------------------|
| <p>【 COPD treatment agent 】 KRP-AB1102 KRP-AB1102F</p> | <p>【Tinnitus treatment agent 】 KRP-209</p> | <p>【Overactive bladder 】 KRP-114V</p> | <p>【Crohn disease】 KRP-203</p> |
| <p>【quinolone antibacterial agent 】 KRP-AM1977X、KRP-AM1977Y</p> | | | |
| <p>【gene therapy】 Ad-SGE-REIC</p> | | | |

Aim to launch new drugs into the market continually by enhancing the pipeline through our own drug discovery and alliance strategy

**Consolidated Financial Results Forecast
for the Year Ending March 31 2015 and
Dividends**

Consolidated Financial Results Forecast for the Year Ending March 31, 2015

(unit : ¥billion)

| | Mar/14 | Mar/15 Revised forecast | Change | % Change | Change from original forecast |
|----------------------------------|--------|----------------------------|--------|----------|-------------------------------------|
| Net Sales | 111.4 | 111.7 | +0.3 | +0.3 | -0.5 |
| Ethical drugs business | 109.7 | 110.0 | +0.3 | +0.3 | -0.5 |
| Healthcare(skincare) Business | 1.7 | 1.6 | -0.1 | -7.1 | -0.1 |
| Operating Income | 17.6 | 13.8 | -3.8 | -21.6 | -2.0 |
| Ordinary Income | 18.3 | 14.3 | -4.0 | -21.8 | -2.0 |
| Net Income | 12.0 | 11.6 | -0.4 | -3.5 | +0.3 |

| | change (y/y) | change (forecast) | Explanation of Variances | |
|-------------------------|----------------------|----------------------|--|---|
| Net sales | new ethical drugs | -2.7 | -2.3 | <ul style="list-style-type: none"> ➢ increase of Flutiform ➢ decrease of main product (Mucodyne, Pentasa, Uritos). ➢ decrease of Gatifloxacin (overseas) |
| | Generic drugs | +3.0 | +2.3 | <ul style="list-style-type: none"> ➢ increase of contract manufacturing's sales and Health insurance pharmacy market's sales |
| Operating Income | -3.8 | -2.0 | <ul style="list-style-type: none"> ➢ gross profit : cost of sales increase due to changes in the product sales mix in the Ethical drugs Business ➢ R&D expense : (year on year +¥2.2, compared to original forecast +¥1.1) ➢ SG&A (exclude R&D) expense : reduce sales costs, labor costs | |
| Net Income | -0.4 | +0.3 | <ul style="list-style-type: none"> ➢ extraordinary income : about 4.5 billion yen for the transfer of the land and building of the former head office building ➢ extraordinary losses : about 1.6 billion yen for the use of the vacant lot of the Pharmaceutical Discovery Research Laboratories | |

【for reference: year on year】

① Cost of sales ratio : increased 2.5% points ② SG&A ratio(include R&D expense): decreased 1% points ③ R&D expense ¥13.6bln(+2.2bln)

Forecast of Mainstay Product Sales and Generic Drugs

(unit : ¥billion)

| | Mar/14 | Mar/15 Revised forecast | Change | % Change | Change from original forecast |
|----------------------|--------|----------------------------|--------|----------|-------------------------------------|
| Kipres | 40.2 | 40.2 | 0 | +0.1 | -0.1 |
| Mucodyne | 18.4 | 13.8 | -4.6 | -24.6 | -2.2 |
| Pentasa | 18.6 | 16.7 | -1.9 | -9.9 | -0.8 |
| Uritos | 8.1 | 7.5 | -0.6 | -6.6 | -0.7 |
| Flutifome | 0.6 | 3.9 | +3.3 | +578.0 | +1.1 |
| Generic Drugs | 12.0 | 15.0 | +3.0 | +25.1 | +2.3 |

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

| | FY13 | FY14 (original forecast) | FY14 (revised forecast) |
|-------------------|----------|-----------------------------|----------------------------|
| Net Income | ¥12.0bln | ¥11.3bln | ¥11.6bln |

Dividends

| | FY13 | FY14 (original forecast) | FY14 (revised forecast) |
|-------------------------------------|----------------------------|-----------------------------|----------------------------|
| Dividend per share (Yen) | ¥52.00 (interim ¥10.00) | ¥52.00 (interim ¥20.00) | ¥52.00 (interim ¥20.00) |
| Consolidated payout ratio(%) | 32.3% | 34.4% | 33.5% |

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

- 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.