

Financial Results for Fiscal 2013

May 12 , 2014
KYORIN Holdings, Inc.
President Masahiro Yamashita



- Outline of Consolidated Financial Results
- Trends of mainstay products
- Status of development pipeline
- Consolidated Financial Results Forecast and Dividends

Outline of Consolidated Financial Results

Outline of Consolidated Financial Results for Fiscal 2013 *Kyorin*

健康はキョーリンの願いです。

(unit : ¥billion)

	FY2012	FY2013	Change	Change(%)	Change (forecast)
Net Sales	107.0	111.4	+4.4	+4.1	-1.2
Operating Income	17.9	17.6	-0.3	-1.9	-0.6
Ordinary Income	18.7	18.3	-0.4	-2.1	-0.5
Net Income	12.4	12.0	-0.4	-3.2	-0.4

Segment Sales

(unit : ¥billion)

		FY2012	FY2013	Change	Change(%)	Change (forecast)
Net Sales		107.0	111.4	+4.4	+4.1	-1.2
Ethical drugs business		105.2	109.7	+4.5	+4.3	-1.2
	Sales of new ethical drugs	90.7	93.5	+2.8	+3.1	-1.6
	Japan	88.3	91.7	+3.4	+3.8	-1.1
	Overseas	2.4	1.8	-0.6	-22.9	-0.5
	Generic drugs	10.1	12.0	+1.9	+18.7	+0.6
	Over-the-counter drugs	4.4	4.2	-0.2	-4.7	-0.1
Healthcare Business		1.9	1.7	-0.2	-7.8	0.0

	Explanation of Variances
new ethical drugs(Japan)	<ul style="list-style-type: none"> •Increased year on year due to Flutiform, fall below forecast (Fultiform , Mucodyne) •increase of royalty (licensing out product) •influence of KYORIN Pharmaceutical Facilities sales (full year)
new ethical drugs(overseas)	<ul style="list-style-type: none"> •sales of Gatifloxacin decreased effect of generic product was launched in USA (sales of Allergan : FY12 \$80MM→FY13 \$61MM) •expenses associated with the income due to transfer of Pekiron assets were posted in the previous year.
Generic drugs	<ul style="list-style-type: none"> •increase of Health insurance pharmacy market's sales and contract manufacturing's sales

Breakdown of Gain and Loss

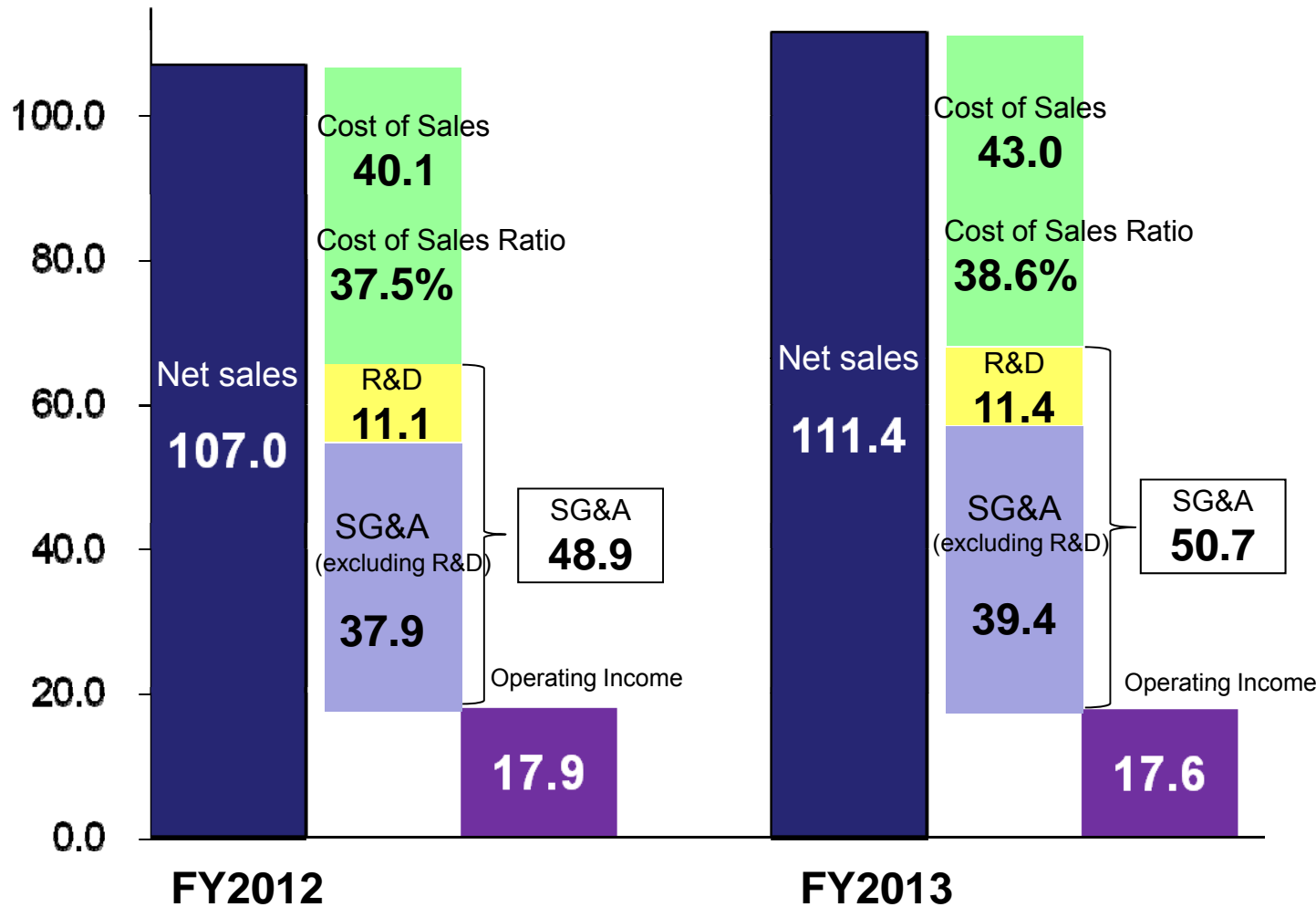
(unit : ¥billion)

	FY2012	FY2013	Change	Change(%)	Change (forecast)
Net Sales	107.0	111.4	+4.4	+4.1	-1.2
Cost of Sales	40.1	43.0	+2.9	+7.3	-
SG&A	48.9	50.7	+1.8	+3.7	-
R&D expenses	11.1	11.4	+0.3	+2.7	-0.4
SG&A expenses	37.9	39.4	+1.5	+4.0	-
Operating Income	17.9	17.6	-0.3	-1.9	-0.6
Ordinary Income	18.7	18.3	-0.4	-2.1	-0.5
Net Income	12.4	12.0	-0.4	-3.2	-0.4

	Explanation of Variances
year on year	<p>➢ <u>gross profit</u> : increased ¥1.5bln (increase of sales ¥4.4bln , cost of sales ratio increased 1.1%) 【reason for increase of cost of sales ratio】increase of generic drugs and KYORIN pharmaceutical Facilities sales</p> <p>➢ <u>SG&A expenses</u> : Increased ¥1.8bln 【reason for increase】R&D expense increased ¥0.3bln (progress of KRP-209 Ph2a) , SG&A (exclude R&D) expense increased ¥1.5bln (increase of sales expenses , patent royalty etc.)</p>
compared to budget	<p>➢ <u>gross profit</u> : fall below forecast (sales fall below forecast , increase of cost of sales ratio) 【reason for increase of cost of sales ratio】effect of exchange rate , low operating rate of facilities</p> <p>➢ <u>SG&A Expenses</u> : fall below forecast 【reason for increase】R&D expense decreased ¥0.4bln, reduced SG&A (exclude R&D) expense</p>

Highlights of Business Performance

(Units: ¥ billion)



Highlight ①

◇ Net Sales increased ¥4.4billion

- increase of Japan new ethical drugs and generic drugs sales
- effect of KYORIN pharmaceutical Facilities sales
- sales of royalty (licensing out product)

Highlight ②

◇ Cost of Sales ratio increased 1.1 percentage points (+¥2.9bln)

◇ Gross Profit increased ¥1.5billion

Highlight ③

◇ SG&A expenses increased ¥1.8billion

- R&D expenses increased ¥0.3billion
- SG&A(excluding R&D) increased ¥1.5billion

Operating Income decreased ¥0.3billion

Mainstay Product Sales

(unit : ¥billion)

	FY2012	FY2013	Change	Change(%)	Change (forecast)
Kipres	39.6	40.2	+0.6	+1.5	-0.1
Mucodyne	19.1	18.4	-0.7	-4.0	-0.4
Pentasa	17.6	18.6	+1.0	+5.3	+0.1
Uritos	7.5	8.1	+0.6	+7.9	+0.1
Flutiform	—	0.6	+0.6	—	-0.4

Trends of mainstay products

Business Strategy (Strategy)

Multi-Core Strategy (MC Strategy)

—Diversify the Consumer Healthcare Business Centering on the Ethical Drug Business—

Ethical Drug Business

Pharma Complex Model

(PC model)



Multi-faceted business development
(New drugs, original drugs,
generic drugs)

Consumer Healthcare Business

Cultivate existing businesses and
create new businesses

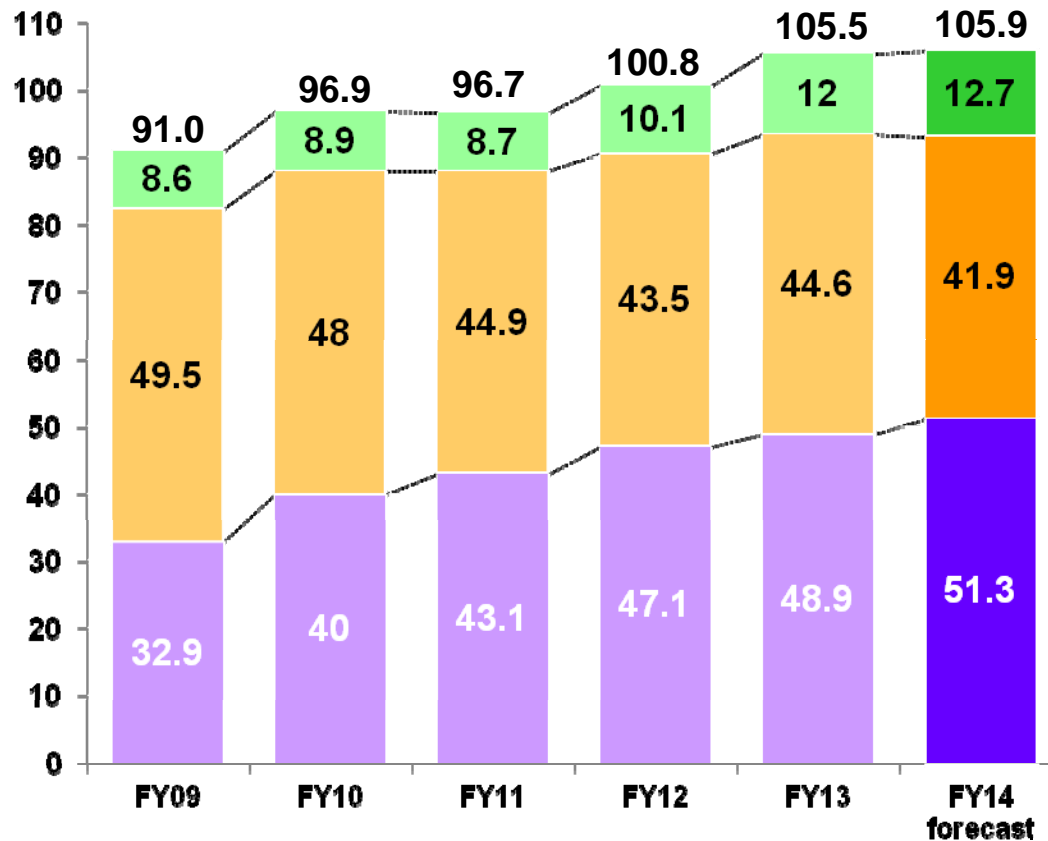
Fiscal 2015 : Sales ¥140.0bIn Operating income ¥20.0bIn

【sales breakdown】Ethical drugs ¥120.0bIn (new drugs ¥50.0bIn, original drugs ¥50.0bIn, generic drugs ¥20.0bIn)

Consumer Healthcare business ¥20.0bIn

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

Flutiform [Anti-asthmatic]

➤ status of FY2013

FY2013 sales : ¥0.6bln

	<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 sales : ¥2.8bln

Aim for dramatic market penetration after the lifting of prescription limitations

• launch of a longer-term prescription formulation

Flutiform 50 Aerosol - 120 inhalations , Flutiform 125 Aerosol - 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

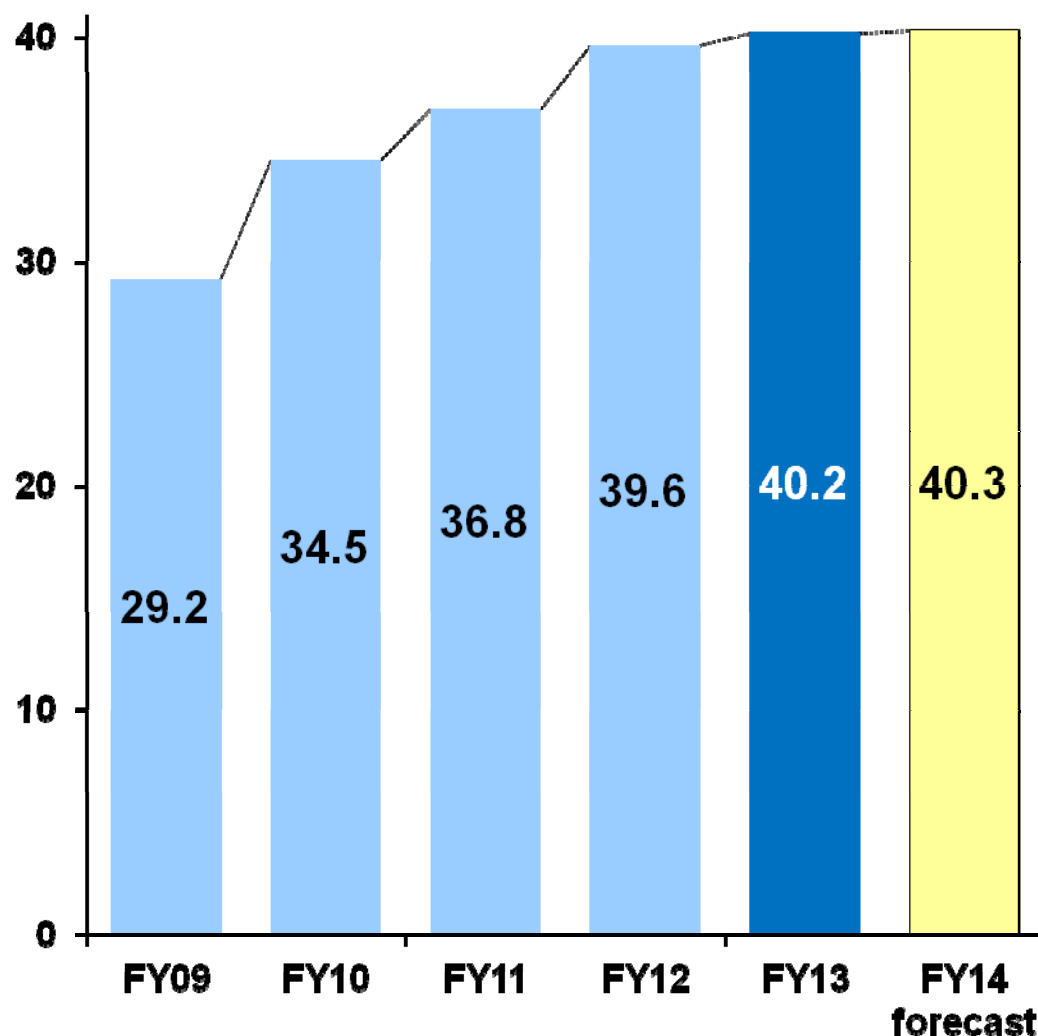
• appeal advantages of pMDI device



■ New drugs group

Kipres 【Bronchial asthma and allergic rhinitis treatment】

(unit : ¥billion)



■ status of FY2013

◆ LT antagonists market : expand 2%

¥125.1bIn (FY2012) ⇒ ¥127.4 (FY2013) ※1

◆ share of Kipres sales

34.9% (FY2012) ⇒ 36.0% (FY2013) ※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

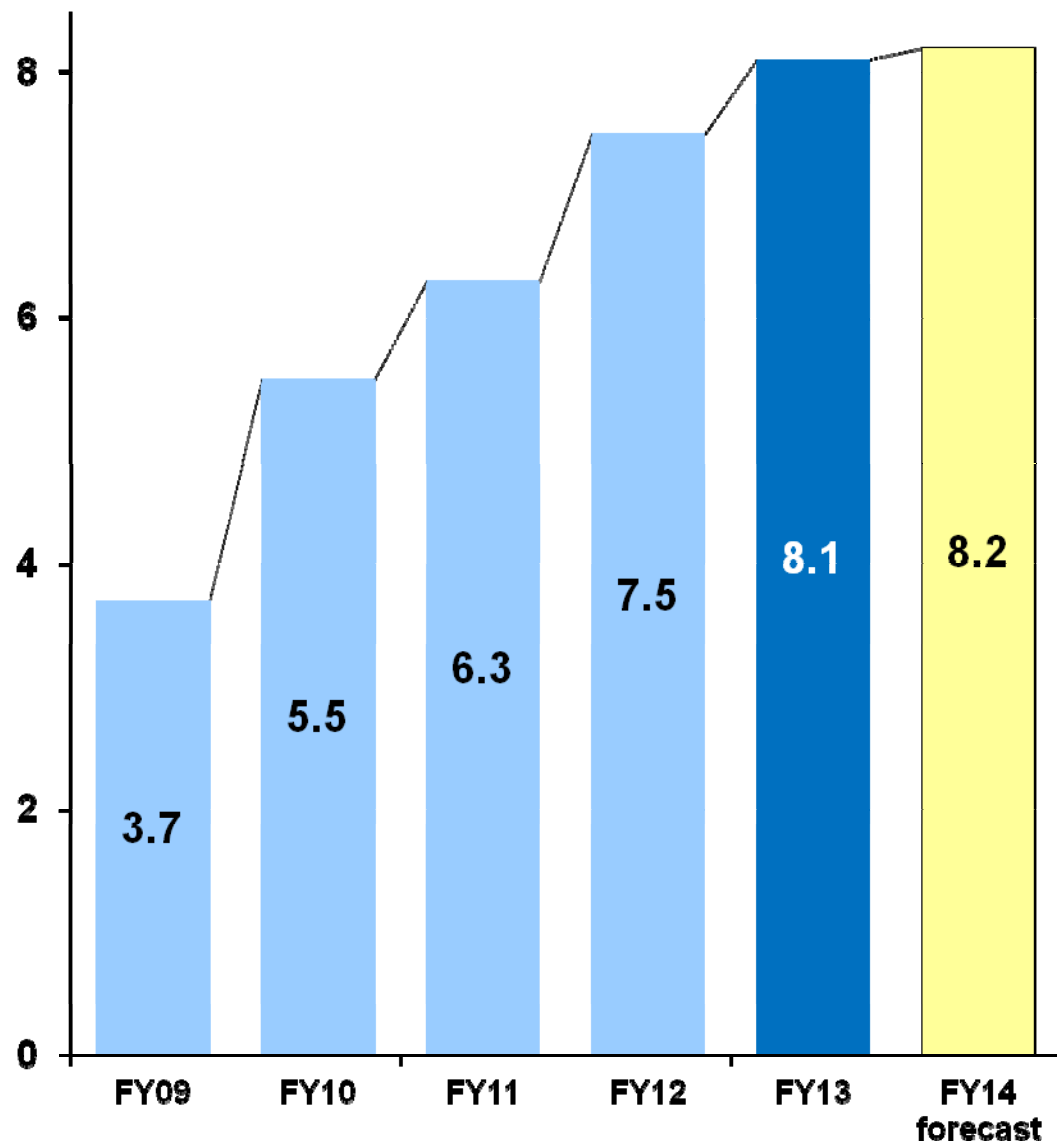
➢ price revision rate ▲7.4%

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■ New drugs group

Uritos 【Overactive bladder】

(unit : ¥billion)



■ status of FY2013

◆ OAB market : expand 11%

¥70.4bln (FY2012) ⇒ ¥77.9bln (FY2013) ※1

◆ share of Uritos sales

11.4% (FY2012) ⇒ 10.9% (FY2013) ※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%

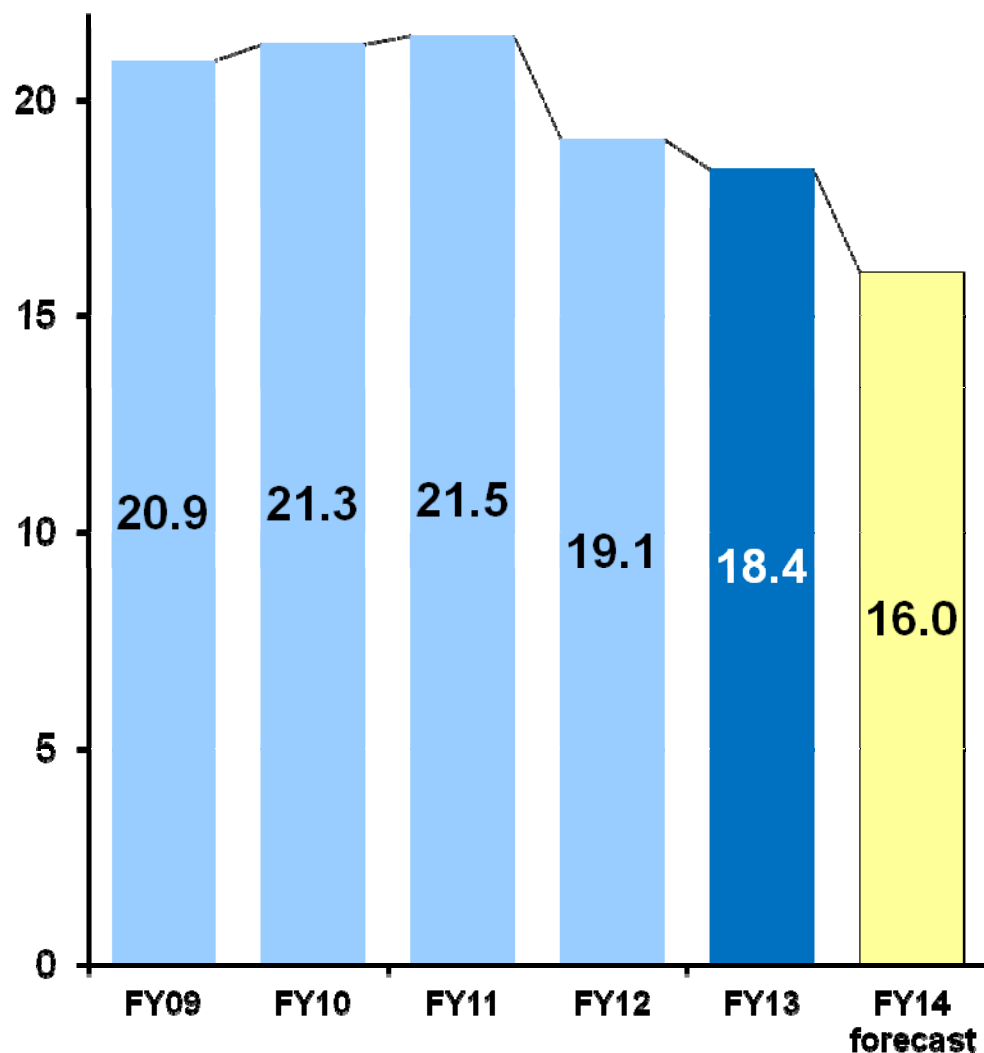
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※3 benign prostatic hypertrophy

■ Original products group

Mucodyne 【 Mucoregulating drug 】

(unit : ¥billion)



■ status of FY2013

● expectorant market : 3% reduction

¥44.9bIn (FY2012) ⇒ ¥43.5bIn (FY2013) ※1

● share of Mucodyne sales

46.9.% (FY2012) ⇒ 46.2% (FY2013) ※2

share of generic (Carbocisteine)

6.3% (FY2012) ⇒ 7.4% (FY2013) ※3

■ effort for FY2014

■ Maximize uptake and prescriptions of 「DS50%」

・prescriptions for upper airway

■ Increase prescriptions based on EBM

・ bronchial asthma , chronic bronchitis
chronic sinus infection etc.

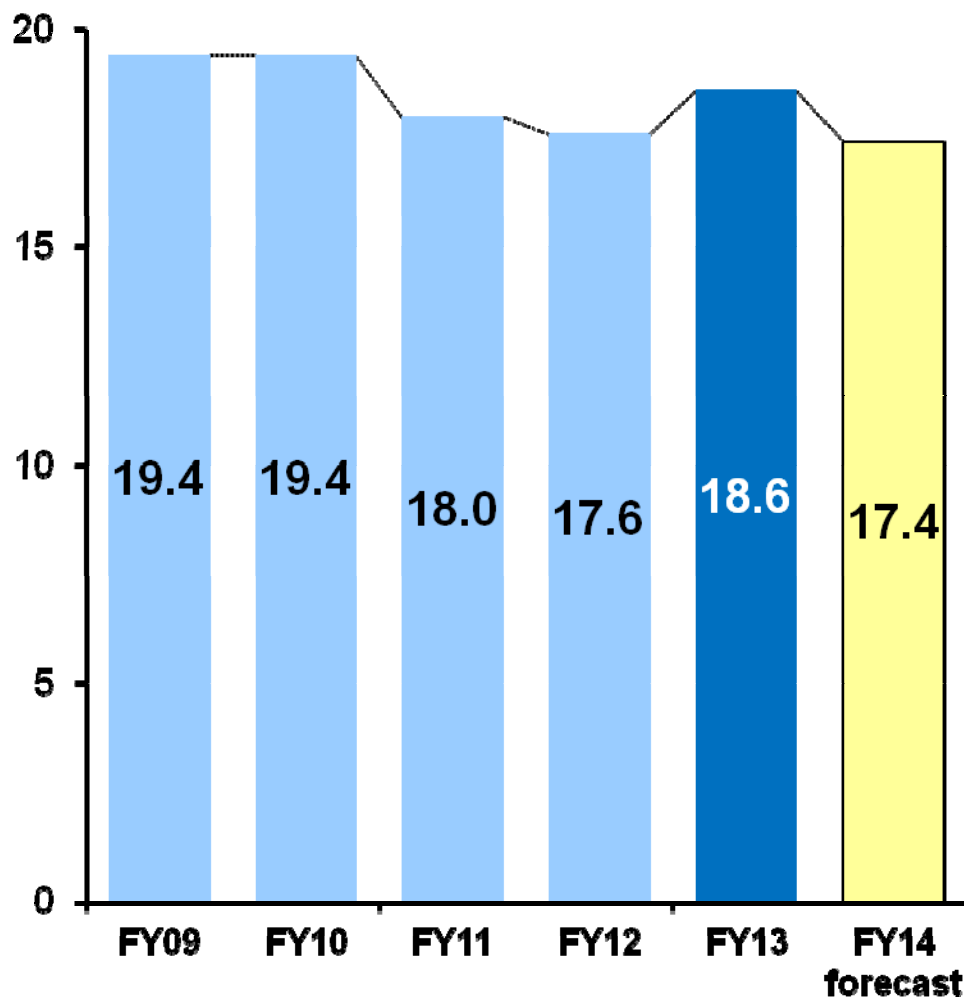
➤ price revision rate ▲6.9%

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Original products group

Pentasa 【Ulcerative colitis and Crohn's disease treatment】

(unit : ¥billion)



status of FY2013

◆ market (Mesalazine etc.) : expand 12%

¥33.8bIn (FY2012) ⇒ ¥37.9bIn (FY2013) ※1

◆ share of Pentasa sales

56.8% (FY2012) ⇒ 52.7% (FY2013) ※2

effort for FY2014

● market penetration of suppositories

FY2013 ¥1.2bIn , FY2014 (forecast) ¥1.5

● prescription for ulcerative colitis active period

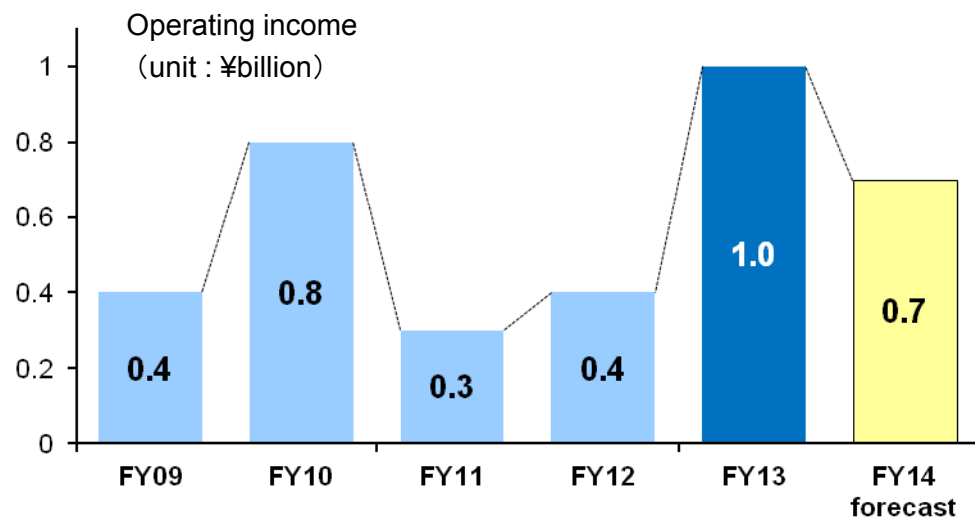
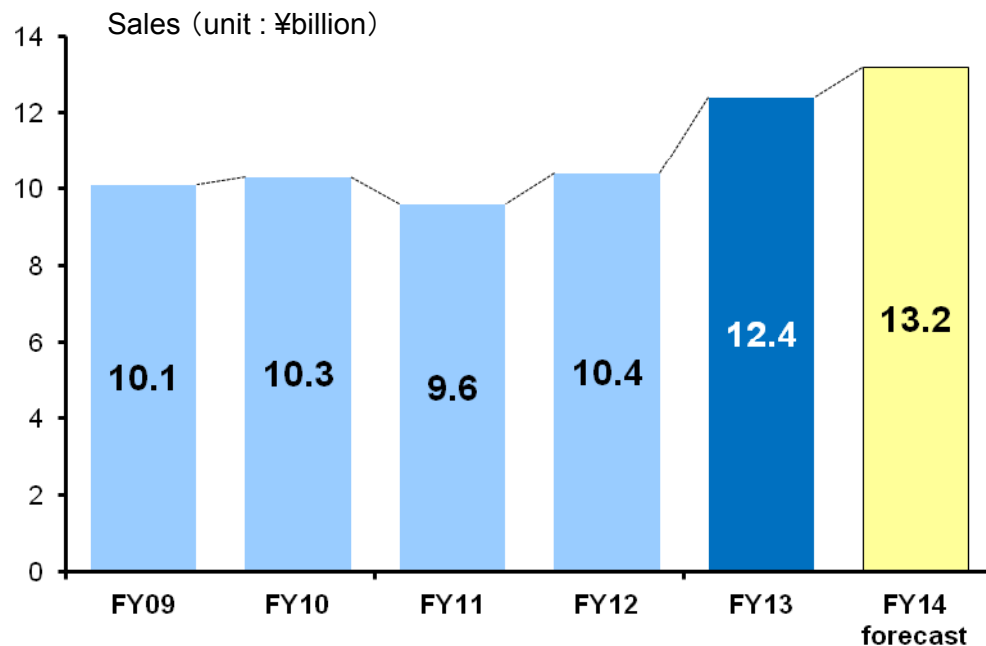
- active period : prescription of 4g twice a day
- remission period : prescription of 2g once a day

➤ price revision rate ▲7.5%

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■ Generic drugs group

Status of Generic Drugs



■ status of FY2013

● sales : ¥12.4bln (+¥2.0bln)

- expand of strategic products and supplementary item
- increase of contract manufacturing sales

● operating income : ¥1.0bln (+0.6bln)

- R&D expense reduced by collaborative development

■ effort for FY2014

➤ promotion of collaborative development

● sales

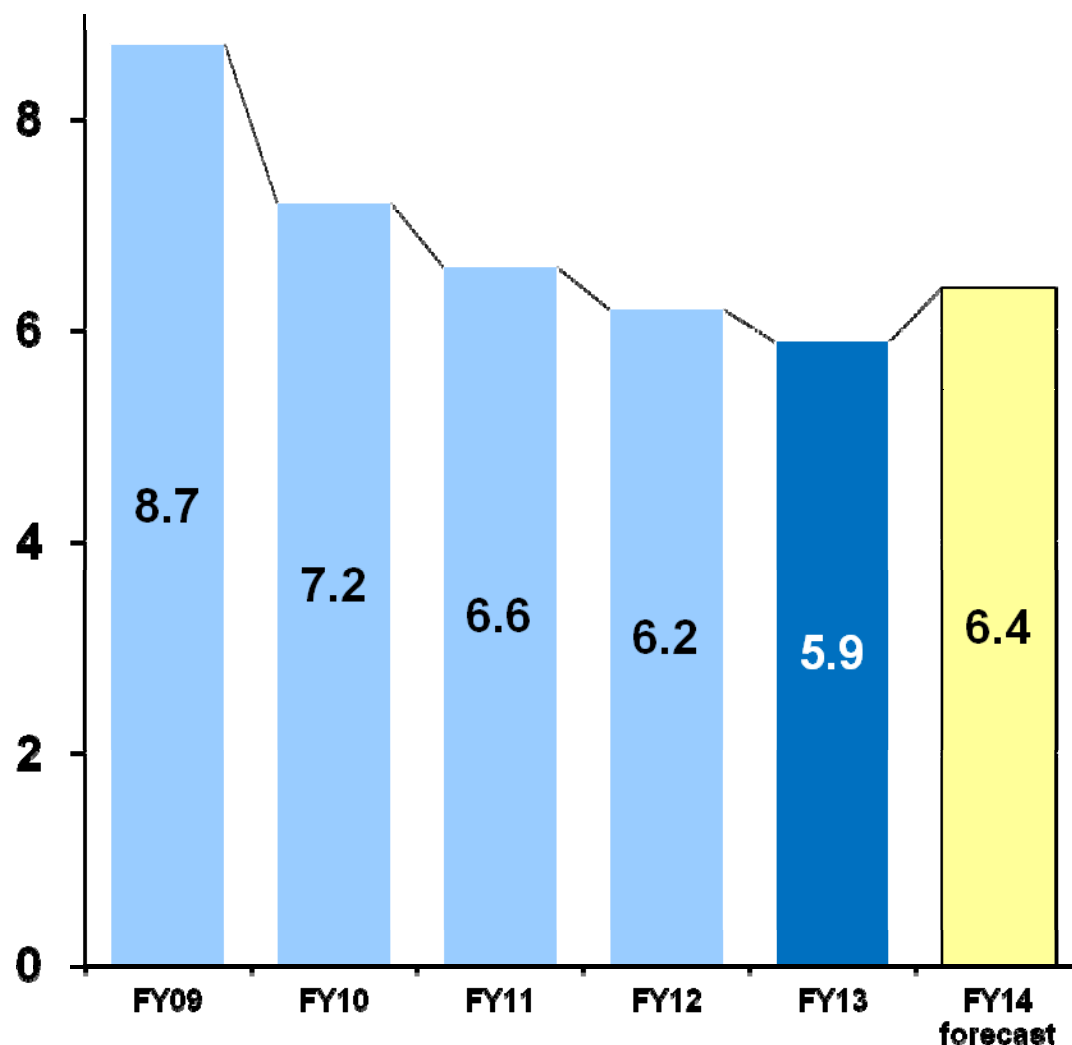
- increase of strategic products and Supplementary Item
- 【strategic product】 Donepezil , Pitavastatin Ca
- 【supplementary item】 Valsartan , Losarhyd combination tablet

● operating income

- **promotion of collaborative development**
- reducing R&D expense by **collaborative development**
- accelerate contract manufacturing

Consumer Healthcare Business (skin care + otc drugs and others)

(unit : ¥billion)



effort for Medium-Term Business Plan
"HOPE 100 – Stage 1 –"

■ Skincare Business

Make business profitable and promote growth
(including development in Asian market)

■ Milton Business, etc.

Leverage the Milton brand to develop new
businesses

■ New Business Creation

Realize our corporate philosophy and create
new businesses that can become the core of
the company in the future (Environmental
Hygiene Business etc.)

Environmental Hygiene business

promote spread of Disinfectant「Milton」and Multi-purpose disinfectant cleaner「RUBYSTA」

●Disinfectant「Milton」

- Strengthen promotion targeting maternity hospitals (increase new adoptions and gain understanding in mothers' classes)
- Grasp how the product is used in medical institutions and facilitate adoption as the in-hospital standard (double retailing with Rubysta).
- FY2014 sales forecast : ¥2.0bln (FY2013 : ¥2.1bln)



●Multi-purpose disinfectant cleaner「RUBYSTA」

- Aim at expanding use through introduction and standardization at hospitals while focusing on Category1,2 facilities eligible for NHI points for measures against infections.
- changing to self-manufacture
- FY2014 sales forecast : ¥0.7bln (FY2013 : ¥0.2bln)



●future effort






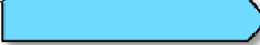
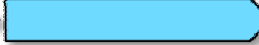















- expand product lineup
 - kit product for helping prevent infection (July 2013 launched)
 - kit product of Multi-purpose disinfectant cleaner「RUBYSTA」 for vomit (Dec 2013 launched)
 -
 -



Status of development pipeline

Drug Development Pipeline: Progress in FY2013

Solid development in all areas of the R&D pipeline

	Product & development code	Ph I	Ph II	Ph III	application	Approval/ Launch
Respiratory	Fultiform					 Nov launch (56inhalations)
	KRP-AB1102				 Mar application	
	KRP-AB1102F			 Sep Ph III		
Urological	KRP-EPA605	 Oct Ph I				
	Aim to in-license products and collaborative development					
Otolaryngological	Kipres Bronchial asthma (1~below the age of 15)			 Apr Ph III		
	KRP-209					
Infections	KRP-AM1977X		 Sep Ph II			
	KRP-AM1977Y					
IBD	Pentasa(UC) suppository					 Jun launch
	KRP-203					

 progress in FY13

Drug Development Pipeline: schedule of FY2014

Aim for an early advance to the next stage in “Respiratory” and “Infections”

	Product & development code	Ph I	Ph II	Ph III	application	Approval/ Launch
Respiratory	Flutiform					Nov launch (120 inhalations)
	KRP-AB1102					Approval
	KRP-AB1102F					
Urological	KRP-EPA605					
Aim to in-license products and collaborative development						
Otolaryngological	Kipres Bronchial asthma (1~below the age of 15)					
	KRP-209					
Infections	KRP-AM1977X			Ph III		
	KRP-AM1977Y		Ph II			
IBD	KRP-203					

schedule of FY14

COPD treatment agent : KRP-AB1102

■ KRP-AB1102

Action : Long-acting muscarine M3 antagonist (LAMA)

Active ingredient : Acclidinium Bromide

Formulation : Dry Powder Inhaler

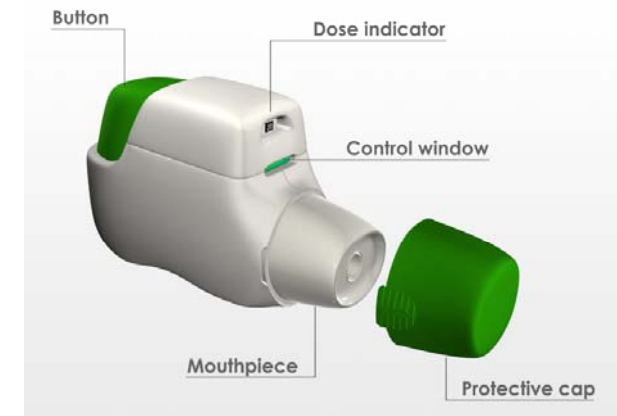
Target disease : COPD

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



Dry powder inhaler : Genuair

Reference

■ KRP-AB1102F

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

- LAMA : Acclidinium Bromide
- LABA : Formoterol

Tinnitus treatment agent : KRP-209

[Outline of clinical study]

- Phase II clinical study (double-blind study)
- Subjects: Patients with subjective tinnitus Sample size: Approx. 400 patients
- Frequency of administration: Twice daily
- 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.

[Future action]

A decision on future action will be made by the end of the second quarter of the fiscal year ending in March 2015.

Consolidated Financial Results Forecast and Dividends

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



(unit : ¥billion)

		FY2013	FY2014 forecast	Change	Change(%)
Net Sales		111.4	112.2	+0.8	+0.7
	Ethical drugs business	109.7	110.5	+0.8	+0.7
	Healthcare(skincare) Business	1.7	1.7	0.0	-1.3
Operating Income		17.6	15.8	-1.8	-10.3
Ordinary Income		18.3	16.3	-2.0	-10.8
Net Income		12.0	11.3	-0.7	-6.0

		FY2014 Forecast	change	Explanation of Variances
Net sales		110.5	+0.8	
	new ethical drugs (Japan)	92.1	+0.4	•drug price revisions (in the 6%range for KYORIN Pharmaceutical). •increase of Flutiform
	new ethical drugs (Overseas)	1.0	-0.8	•decrease of Gatifloxacin (sales of Allergan: FY13 \$61MM→FY14 \$23MM)
	Generic drugs	12.7	+0.7	•increase of Health insurance pharmacy market's sales and contract manufacturing's sales
	Over-the-counter drugs	4.6	+0.4	•Increase of Rubysta

Operating Income	15.8	-1.8	<p>>gross profit</p> <p>•decrease year on year, effect of cost of sales ratio(increase approximately 1% year on year) 【reason for increase of cost of sales ratio】 drug price revisions , decrease of Gatifloxacin, increase of generic product</p> <p>>R&D expense : ¥12.5bIn (+¥1.1bIn year on year) progress of pipeline(KRP-AB1102F, KRP-AM1977X etc.)</p> <p>>SG&A Expenses (excluding R&D Expenses)</p> <p>•R&D ratio decrease approximately 1% year on year</p>
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Forecast of Mainstay Product Sales

(unit : ¥billion)

	FY2013	FY2014 Forecast	Change	Change(%)
Kipres	40.2	40.3	+0.1	+0.4
Mucodyne	18.4	16.0	-2.4	-12.7
Pentasa	18.6	17.5	-1.1	-5.8
Uritos	8.1	8.2	+0.1	+2.1
Flutiform	0.6	2.8	+2.2	+390.3

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

	FY2013 (forecast)	FY2013
Net Income	¥12.4bln	¥12.0bln

FY2014 (forecast)
¥11.3bln

Dividends

	FY2013 (forecast)	FY2013
Dividend per share (Yen)	¥52.00 (interim ¥10.00)	¥52.00 (interim ¥10.00)
Consolidated payout ratio(%)	31.2%	32.3%

FY2014 (forecast)
¥52.00 (interim ¥20.00)
34.4%