

Interim Term Financial Results Ended September 2015

**November 6 , 2015
KYORIN Holdings, Inc.
President Minoru Hogawa**



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

Outline of Consolidated Financial Results

Outline of Consolidated Financial Results for the Interim Term Ended September 2015

(unit : ¥billion)

	Sep/14	Sep/15	Change	Change(%)	Change (forecast)	Mar/15	Mar/16 (forecast)
Net Sales	51.1	52.4	+1.3	+2.5	-2.0	113.1	120.2
Operating Income	4.6	4.1	-0.5	-10.6	+0.3	14.7	16.0
Ordinary Income	4.9	4.3	-0.6	-12.9	+0.3	15.5	16.3
Net Income	3.5	3.0	-0.5	-15.1	+0.4	12.1	11.5

※The results forecasts for the full year announced on May 13, 2015 remain unchanged.

Segment Sales

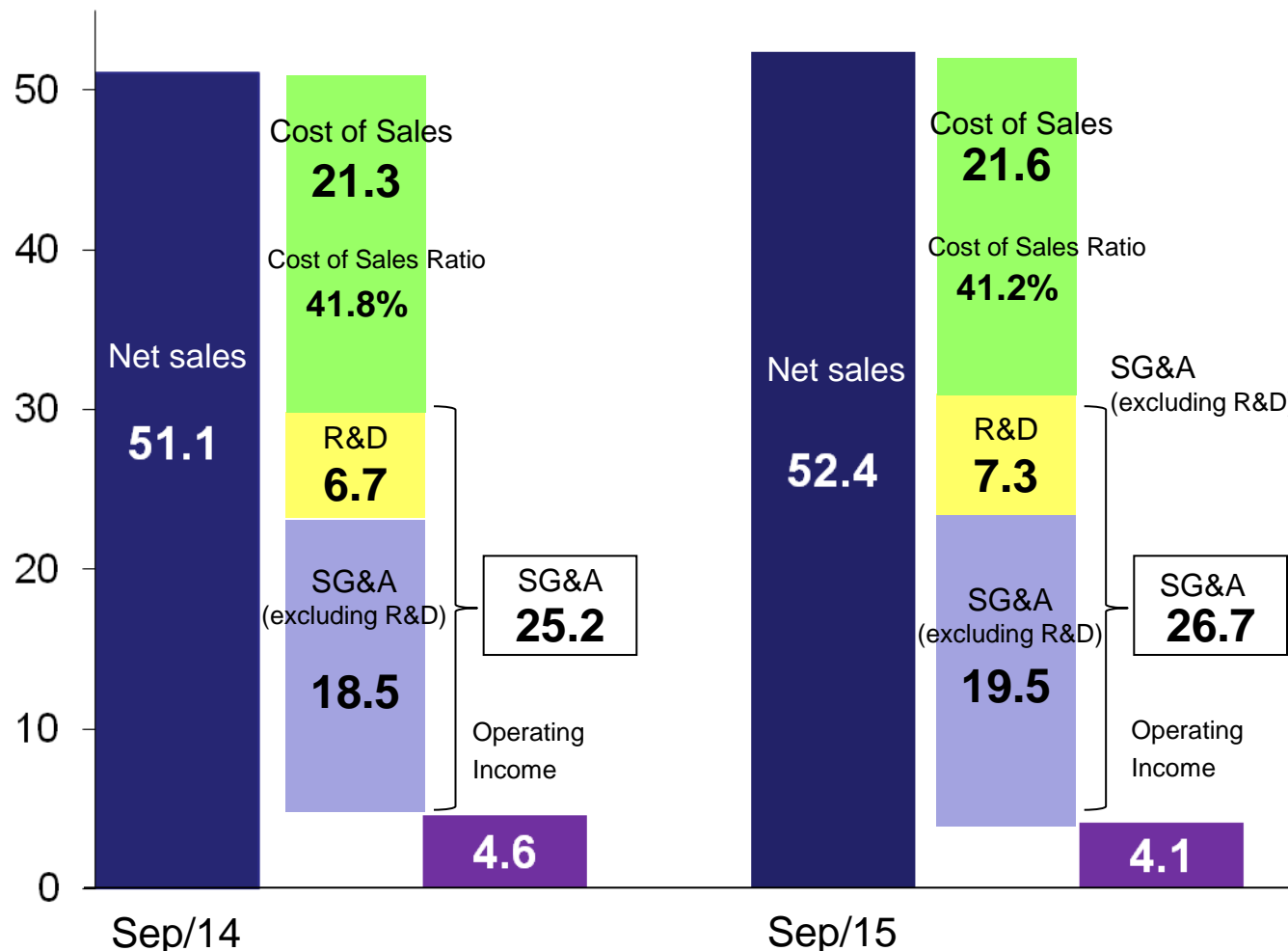
(unit : ¥billion)

			Sep/14	Sep/15	Change	Change(%)	Change (forecast)
Net Sales			51.1	52.4	+1.3	+2.5	-2.0
			50.5	51.8	+1.3	+2.5	-1.9
Ethical drugs business	Sales of new ethical drugs		40.8	42.2	+1.4	+3.6	-0.7
		Japan	40.4	41.6	+1.2	+3.0	-0.9
		Overseas	0.3	0.6	+0.3	+78.7	+0.2
	Generic drugs		7.8	7.4	-0.4	-5.1	-1.3
	Over-the-counter drugs		2.0	2.2	+0.2	+9.5	+0.2
Healthcare Business			0.6	0.6	0.0	+1.7	-0.1

	change (y/y)	change (forecast)	Explanation of Variances
New ethical drugs (Japan)	+1.2	-0.9	<ul style="list-style-type: none"> ➢ Main product(Flutiform, Kipres, etc.) increased year on year ➢ Flutiform decreased compared to forecast
New ethical drugs (overseas)	+0.3	+0.2	<ul style="list-style-type: none"> ➢ sales of Gatifloxacin increased (sales of Allergan: FY14 second half \$14MM→FY15 second half \$14MM)
Generic drugs	-0.4	-1.3	<ul style="list-style-type: none"> ➢ increase of Health insurance pharmacy market's sales , decrease of Contract manufacturing's sales ➢ Health insurance pharmacy market's and Contract manufacturing's sales decreased compared to forecast

Highlights of Business Performance

(Units: ¥billion)



➤ **Net Sales increased ¥1.3billion year on year.**

- increase of main products (Flutiform, Mucodyne, Uritos)

➤ **Cost of sales ratio decreased 0.6%.**

- Sales of main product increased
- Sales of generic drugs decreased

■ **Gross Profit increased ¥1.0billion year on year**

➤ **SG&A expenses increased ¥1.5billion year on year.**

- R&D expenses increased ¥0.6billion (cost of new WATARASE research center, progress of project)
- SG&A(excluding R&D) increased ¥1.0billion (increase of patent royalty, sales costs)

■ **Operating Income decreased ¥0.5billion year on year.**

Breakdown of Gain and Loss

(unit : ¥billion)

	Sep/14	Sep/15	Change	Change(%)	Change (forecast)
Net Sales	51.1	52.4	+13	+2.5	-2.0
Cost of Sales	21.3	21.6	+3	+1.0	-
SG&A	25.2	26.7	+15	+6.1	-
R&D expenses	6.7	7.3	+6	+8.9	-0.1
SG&A expenses	18.5	19.5	+10	+5.1	-
Operating Income	4.6	4.1	-5	-10.6	+0.3
Ordinary Income	4.9	4.3	-6	-12.9	+0.3
Net Income	3.5	3.0	-5	-15.1	+0.4

	change (y/y)	change (forecast)	Explanation of Variances
Operating Income	-0.5	+0.3	<p>【y / y】</p> <p>•Gross profit rose 1 billion yen year on year due to increase of sales and decrease in the cost ratio. At the other side, SG & A expenses increased 1.5 billion yen (R&D expense increased 0.6 billion yen) year on year , consequently, operating income decreased 0.5 billion yen year on year.</p> <p>【forecast】</p> <p>•Gross profit decreased forecast due to fall of sales. At the other side, SG & A expenses(sales expense) decreased , consequently, operating income increased 0.3 billion yen year on year.</p>

Mainstay Product Sales

(unit : ¥billion)

	Sep/14	Sep/15	Change	Change(%)	Change (forecast)
Kipres	17.4	18.8	+1.4	+7.9	+0.7
Flutiform	0.9	3.0	+2.1	+216.2	-1.1
Uritos	3.4	3.7	+0.3	+9.3	-0.1
Mucodyne	6.2	5.9	-0.3	-3.6	+0.7
Pentasa	8.6	8.1	-0.5	-5.9	-0.3

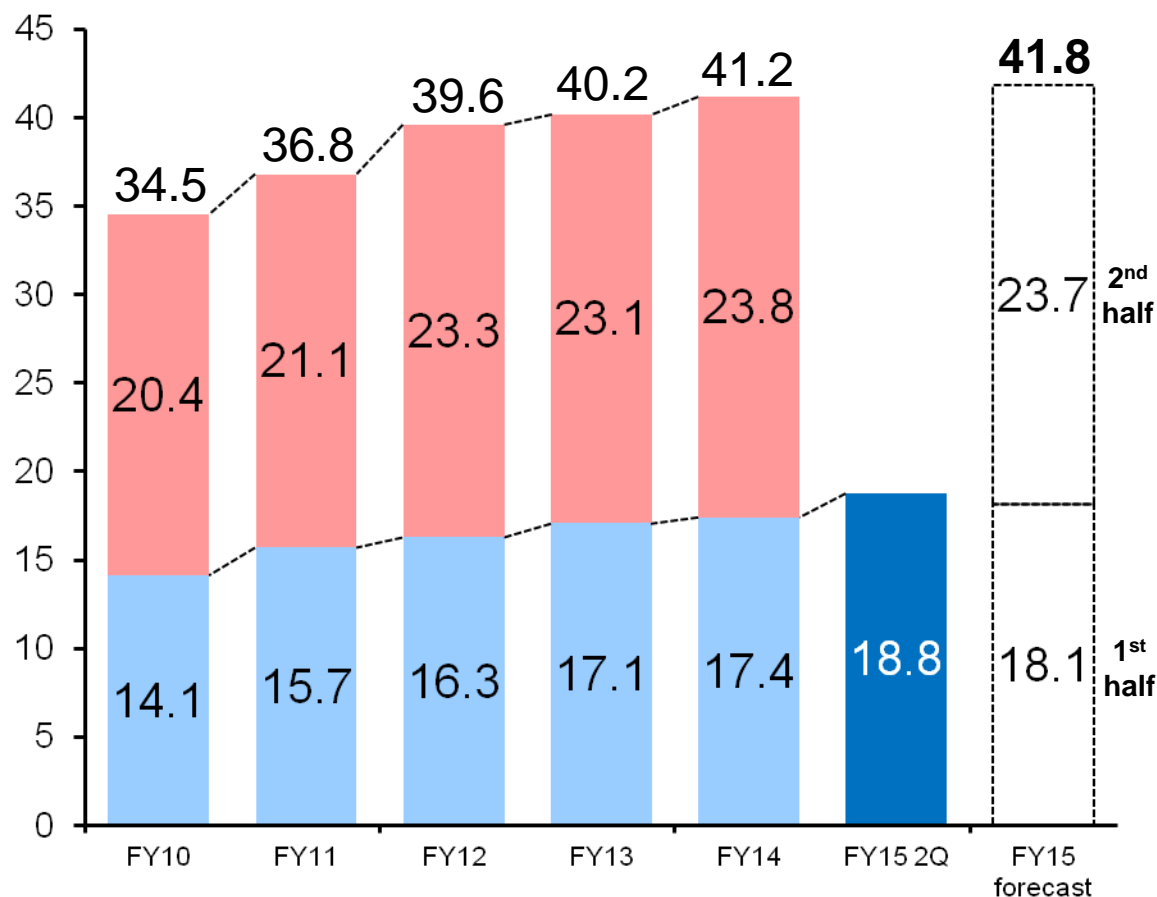
Generic drugs	7.8	7.4	-0.4	-5.1	-1.3
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Trends of mainstay products

■ New drugs group

Kipres 【Bronchial asthma and allergic rhinitis treatment】

Sales (unit : ¥billion)



■ status in first half 2015

- **LT antagonists market : expand 5%**
 ¥56.2bln (FY14 first half) ⇒ ¥58.8bln (FY15 first half) ※1
 - **share of Kipres sales**
 37.2% (FY14 first half) ⇒ 38.5% (FY15 first half) ※2
- ※ Both allergic rhinitis, and asthma prescription expanded

■ effort for FY2015

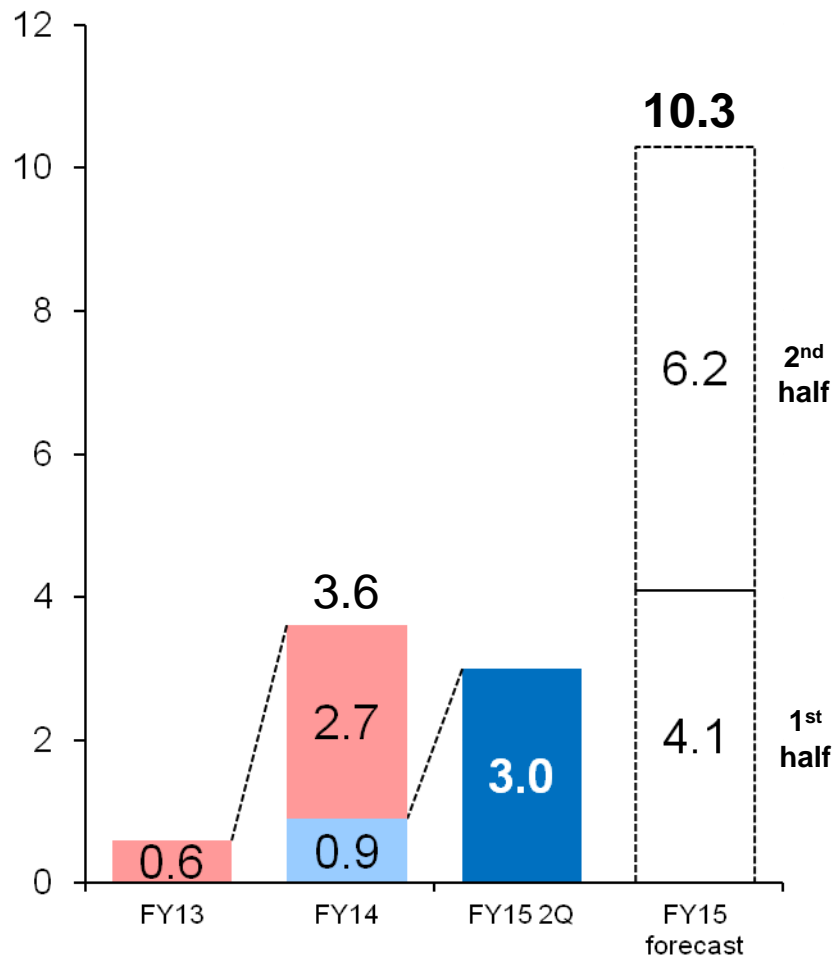
- **Establish position as base drug for treatment of allergic rhinitis(perennial and seasonal) and growth in new prescriptions**
- **Further promote prescription to asthma patient**
- **Improvement of product value in the life cycle management**
 - ・「KIPRES® OD Tablets 10mg」: **Approval in August 2015**
 (the drug price in Japan is due to list on December)

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■ New drugs group

Flutiform 【Anti-asthmatic】

Sales (unit : ¥billion)



■ Status in first half 2015

● ICS/LABA market : expand 17%

¥43.8bln (FY14 first half) ⇒ ¥51.4bln (FY15 first half) ※1

● share of Flutiform sales

7% (September 2015) ※2

■ effort for FY2015

● 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
- New prescriptions acquisition (treatment interruption and, patients of exacerbation)

● 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.)

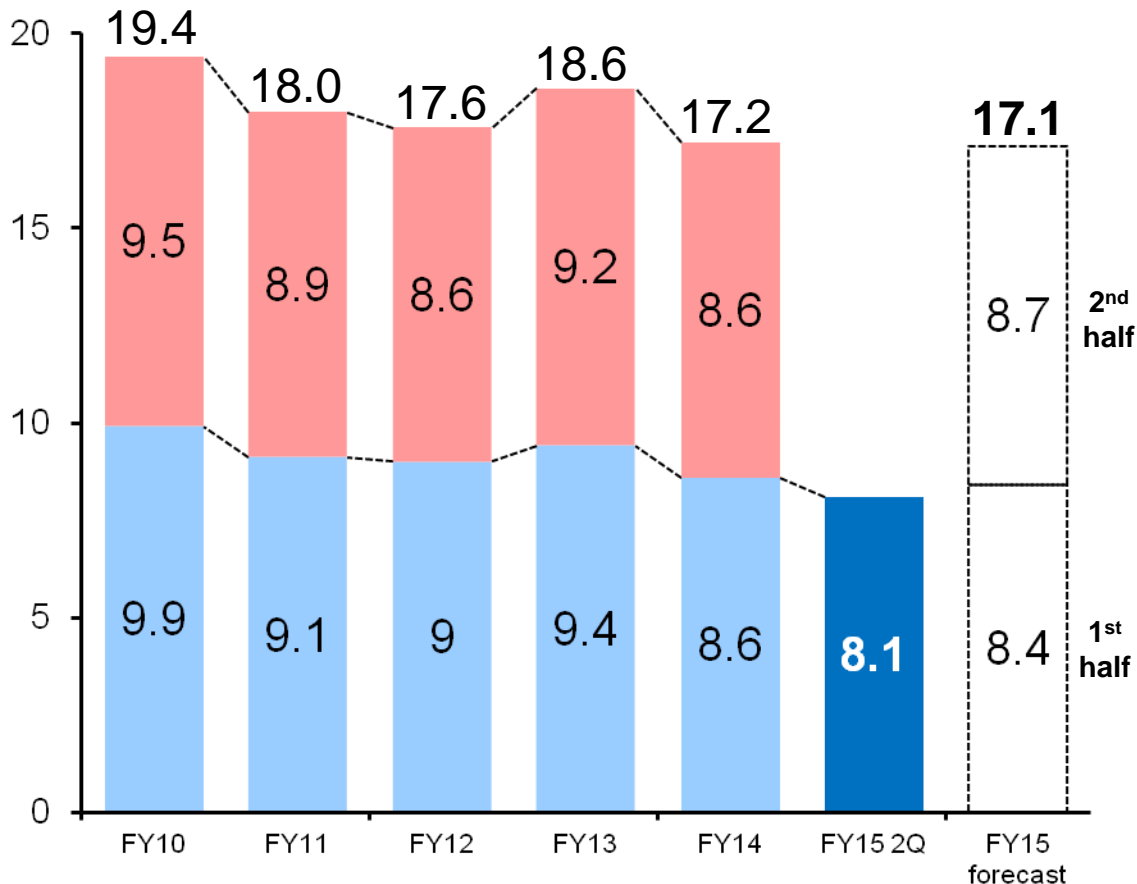
● Further promote prescription of a longer-term prescription formulation(30days,120 inhalations)

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Original products group

Pentasa 【Ulcerative colitis and Crohn's disease treatment】 生産はキョーリンの願いです。

Sales (unit : ¥billion)



status in first half 2015

- **market (Mesalazine etc.) : expand 4%**
 - ¥18.9bln (FY14 first half) ⇒ ¥19.6bln (FY15 first half) ※1
- **share of Pentasa sales**
 - 51.6% (FY14 first half) ⇒ 46.7% (FY15 first half) ※2

effort for FY2015

- **Improvement of product value in the life cycle management**
 - 「PENTASA Granules 94%」: Approval in August 2015 (the drug price in Japan is due to list on December)
- **Organization of IBD task force to start promotion (October)**
- **market penetration of suppositories**
 - FY2015 first half sales : ¥0.9bln、FY2015 (forecast) ¥1.9bln

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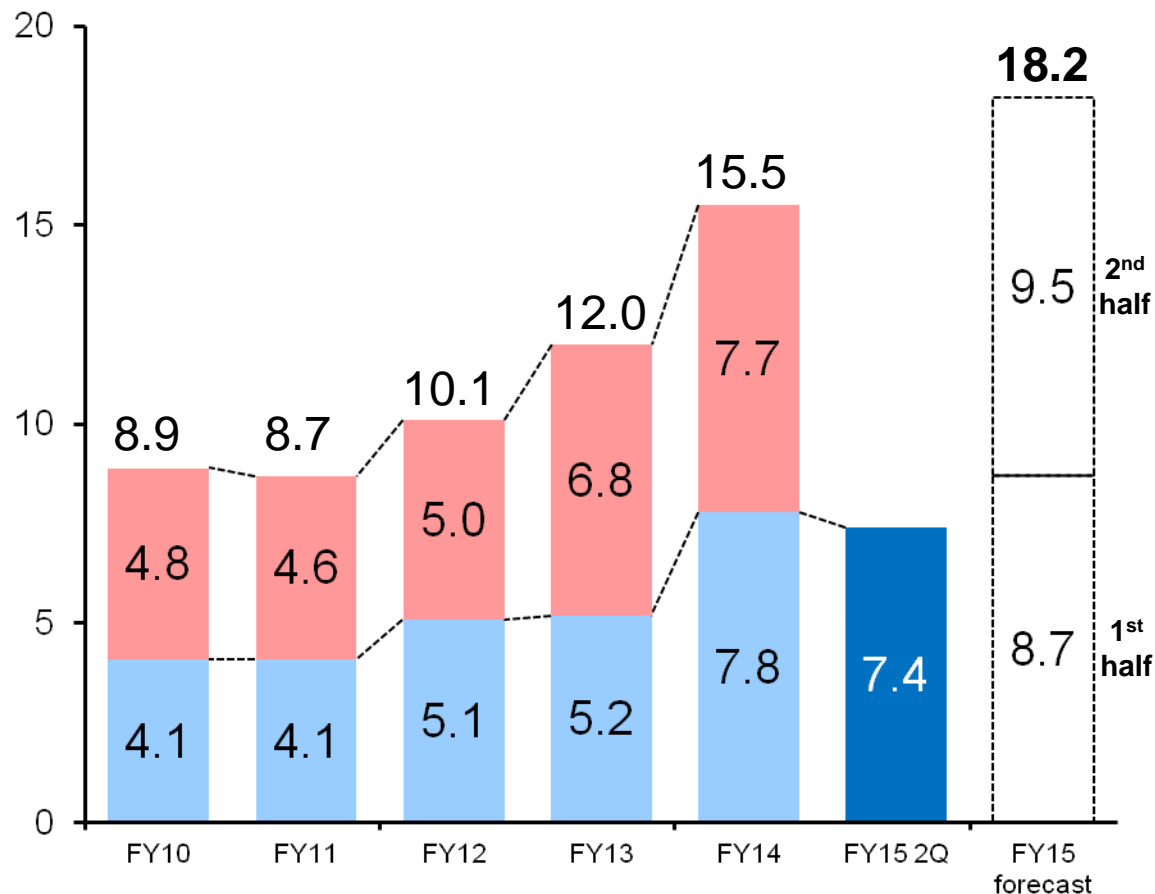
Advantages of "PENTASA Granules 94%" in terms of administration

Reduces the burden on a patient taking medicine in terms of dosage form (tablet size) or number of tablets, leading to simple drug administration

「PENTASA Tablets 250mg」 × 8 tablets OR 「PENTASA Tablets 500mg」 × 4 tablets → 「PENTASA Granules 94% 2000mg」 × 1 package

Generic drugs

Sales (unit : ¥billion)



■ Status in first half 2015

- Sales of Health insurance pharmacy market's decreased compared to forecast
 - ・ Supplementary Item and main products etc.
- Sales of Contract manufacturing decreased compared to forecast

■ effort for FY2015

- increase of strategic products and Supplementary Item
 - 【June supplementary Item】 Clopidogrel, Naftopidil
 - 【Dec supplementary Item】 Amvalo, sertraline
- Promote in-house development and contracting work

Consolidated Financial Results Forecast and Dividends

Consolidated Financial Results Forecast for the Year Ending March 31, 2016

(unit : ¥billion)

		FY2014	FY2015 forecast	Change	Change(%)
Net Sales		113.1	120.2	+7.1	+6.3
	Ethical drugs business	111.8	118.6	+6.8	+6.1
	Healthcare(skincare) Business	1.3	1.6	+0.3	+25.5
Operating Income		14.7	16.0	+1.3	+8.6
Ordinary Income		15.5	16.3	+0.8	+5.2
Net Income		12.1	11.5	-0.6	-4.7

		FY2015 Forecast	change	Explanation of Variances
Net sales	new ethical drugs (Japan)	94.7	+3.6	•increase of new ethical drugs , such as Flutiform
	new ethical drugs (Overseas)	1.0	0.0	(sales of Allergan : FY14 \$32MM→FY15 \$23MM)
	Generic drugs	18.2	+2.7	•increase of Health insurance pharmacy market's sales
Operating Income		16.0	+1.3	>gross profit •We expect gross profit rise due to the increase of net sales. >R&D expense : ¥13.4bln (-¥0.1bln year on year) >SG&A Expenses (excluding R&D Expenses) : increase of sales and labor costs

【for reference: year on year】

①Cost of sales ratio : increased 1% points ② SG&A ratio(include R&D expense): decreased 1% points

※The results forecasts for the full year announced on May 13, 2015 remain unchanged.

Forecast of Mainstay Product Sales

(unit : ¥billion)

	FY2014	FY2015 Forecast	Change	Change(%)
Kipres	41.2	41.8	+0.6	+1.5
Flutiform	3.6	10.3	+6.7	+185.4
Uritos	7.3	7.9	+0.6	+9.4
Mucodyne	14.0	11.8	-2.2	-15.6
Pentasa	17.2	17.1	-0.1	-0.3
Generic drugs	15.5	18.2	+2.7	+17.6

※The results forecasts for the full year announced on May 13, 2015 remain unchanged.

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

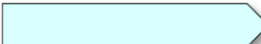

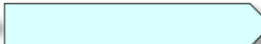

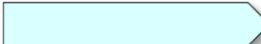










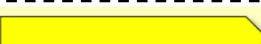




	FY14	FY15 (forecast)
Net Income	¥12.1bln	¥11.5bln

Dividends

	FY14	FY15 (forecast)
Dividend per share (Yen)	¥52.00 (interim ¥10.00)	¥52.00 (interim ¥20.00)
Consolidated payout ratio(%)	32.2%	33.8%

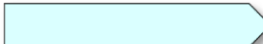

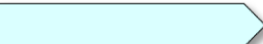

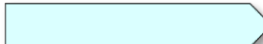

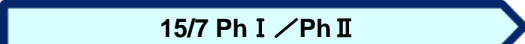









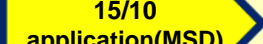


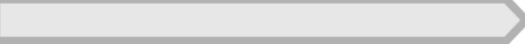
Status of development pipeline

Drug Development Pipeline : schedule of FY2015

	Product & development code	Ph I	Ph II	Ph III	application	Approval/ Launch
Respiratory	Eklira Genuair					
	KRP-AB1102F					
	Ad-SGE-REIC					
Infections	KRP-AM1977X					
	KRP-AM1977Y					
Otolaryngological	KRP-209					
	Desloratadine <small>Co-Marketing Agreement for Japan with MSD K.K. affiliate.</small>					
Urological	KRP-114V					
IBD						
	KRP-203					

 schedule of FY2015

Drug Development Pipeline : Progress in FY2015

	Product & development code	Ph I	Ph II	Ph III	application	Approval/ Launch
Respiratory	Eklira Genuair					 15/5 launch
	KRP-AB1102F					
	Ad-SGE-REIC	 15/7 Ph I / Ph II				
	Kipres OD					 15/8 approval
Infections	KRP-AM1977X			 15/4 Ph III		
	KRP-AM1977Y					
Otolaryngological	KRP-209		 15/8 Ph II			
	Desloratadine <small>Co-Marketing Agreement for Japan with MSD K.K. affiliate.</small>				 15/10 application(MSD)	
Urological	KRP-114V					
IBD	Pentasa Granules					 15/8 approval
	KRP-203			discontinued of IBD		



 progress of FY2015

Novartis has decided to proceed with development of KRP-203 for GvHD.

- Mode of action : Sphingosine-1-Phosphate Receptor Agonist
- Business partner : Novartis (License agreement executed on February 2006)

Based on the data in the various clinical trials conducted worldwide, the competing products and the priorities in our pipeline, we decided to focus on the development in GvHD indication and discontinued the development in IBD.

Current status and prospects of GvHD treatment

◆ Graft-versus-host disease (GvHD):

Alloreactive lymphocyte driven reaction that occurs after hematopoietic stem cell transplantation. Skin, liver and intestine are most frequently affected.

◆ Current treatment of GvHD:

Steroids and immunosuppressants are commonly treated for GvHD patients, but often result in inadequate control or poor prognosis due to lack of efficacy or adverse effects. Thus, major current challenges are reducing the onset of severe GvHD symptoms and subsequent mortality.

Number of patients (allogeneic haemopoietic stem cell transplantation):

22,000 cases/year (worldwide); 3,500 cases/year (Japan)

Our priority aim is to develop KRP-203 as a treatment for GvHD, which constitutes an area of high unmet medical needs worldwide.

Antiallergic Agent「 Desloratadine」

- Co-Marketing Agreement for Japan with MSD K.K. affiliate(November 2014)
- MSD Submits New Drug Application(October 2015)

【 Details of application】

Features: second generation histamine H1-receptor antagonist

Compound: Desloratadine

Therapy area/Action: allergic rhinitis, hives, itching resulting from skin diseases (eczema/dermatitis, pruritus cutaneous)

Dosage and administration: Once daily

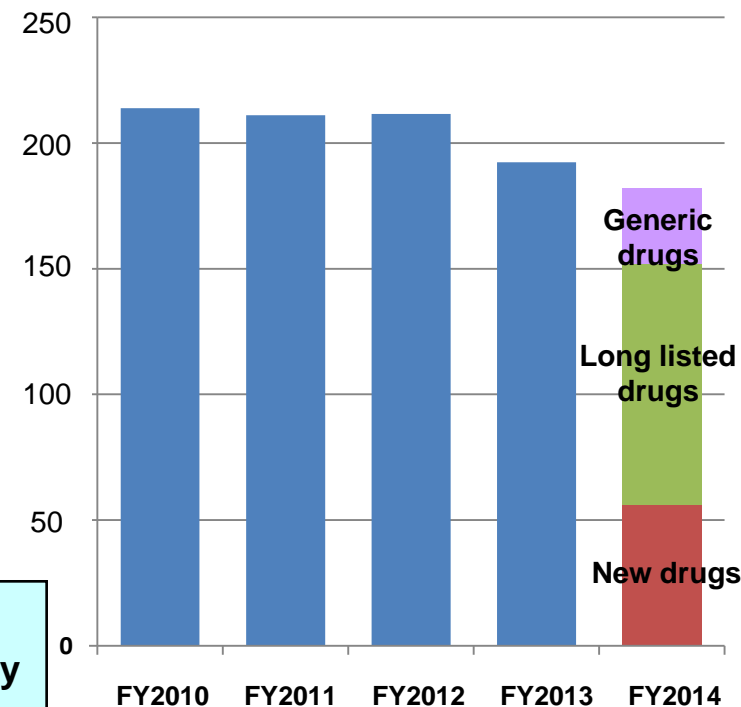
Marketing method : Co-Marketing for Japan with MSD K.K.

【Features】

- High affinity for a histamine receptor and low central nerve transition
- New 2nd-generation antihistamine drug with balanced efficacy and safety

【 Antihistamine market】

(unit : ¥billion)



■International Nonproprietary Name : **lascufloxacin** (r-INN)

【 Features 】

- Have a broad antibacterial spectrum from Gram-positive bacteria to Gram-negative bacteria and atypical bacteria. Also have stronger antibacterial activity to anaerobic bacteria than similar agents.
- High safety (QT prolongation, abnormal blood glucose level, photosensitivity, digestive symptom, etc.) is expected.

Status of development : KRP-AM1977X (Oral agent)

●Clinical trials: Ph2 : Results (announced in May 2015)

- ◆ Evaluated efficacy and safety for patients with mild to moderate community acquired pneumonia
 - High efficacy with low dose is confirmed
 - High safety is suggested

●Clinical trials: Ph3 (started in April 2015)

◆Respiratory field

Study design: Double-blind comparative study in patients with community acquired pneumonia

◆Otorhinolaryngology field

Study design: Double-blind comparative study in patients with sinusitis

Status of development : KRP-AM1977Y (Injection)

●Clinical trials: Ph2 : Results (announced in November

- ◆ Evaluated efficacy and safety for patients with mild to severe community acquired pneumonia
 - High efficacy including early therapeutic effect is confirmed
 - High safety is suggested

●Clinical trials: Ph3 :

To be prepared

Aim for early application and commercialization

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. ※1
- Creation of the conditional/time limited approval system (Nov/2014)※2

Started clinical trial (Ph1 / Ph2) In July 2015
Target disease : Malignant Pleural Mesothelioma

※1 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.

※2 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.

[November 2015] Peptide Discovery Collaboration Agreement with PeptiDream Inc.

Collaboration by using PDPS* technology to generate macrocyclic/constrained peptides against target protein.

[Summary]

- Use PeptiDream's proprietary PDPS technology, which we consider to be one of the new drug discovery approaches, to generate macrocyclic/constrained peptides with a high affinity for specific targets of interest.
- Promote clinical development and commercialization of new drugs that are easy to use and have excellent therapeutic efficacy in the priority area/disease selected by our company.

※ PDPS (Peptide Discovery Platform System)

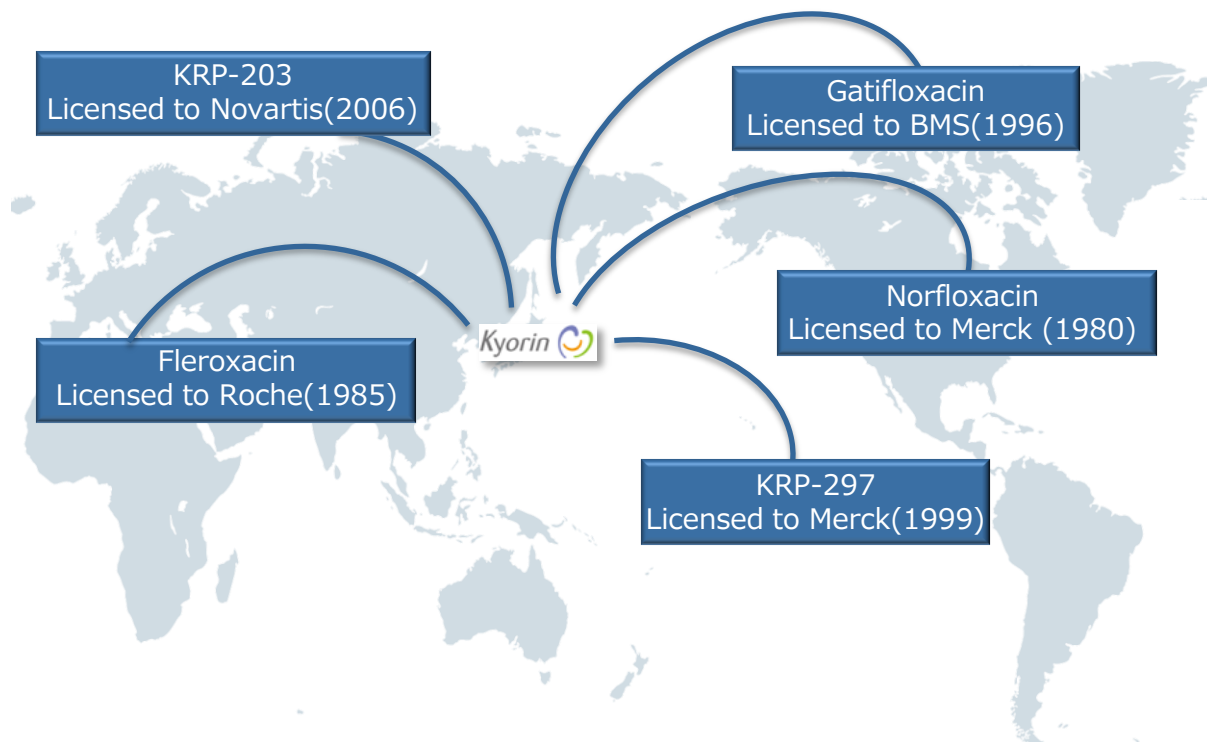
about our future drug discovery

Aim to become a manufacture of original new drugs that can contribute to the health of the world's people.

[a new Pharmaceutical Discovery Research Laboratories]
WATARASE Research Center



History of KYORIN Pharmaceutical's drug discovery

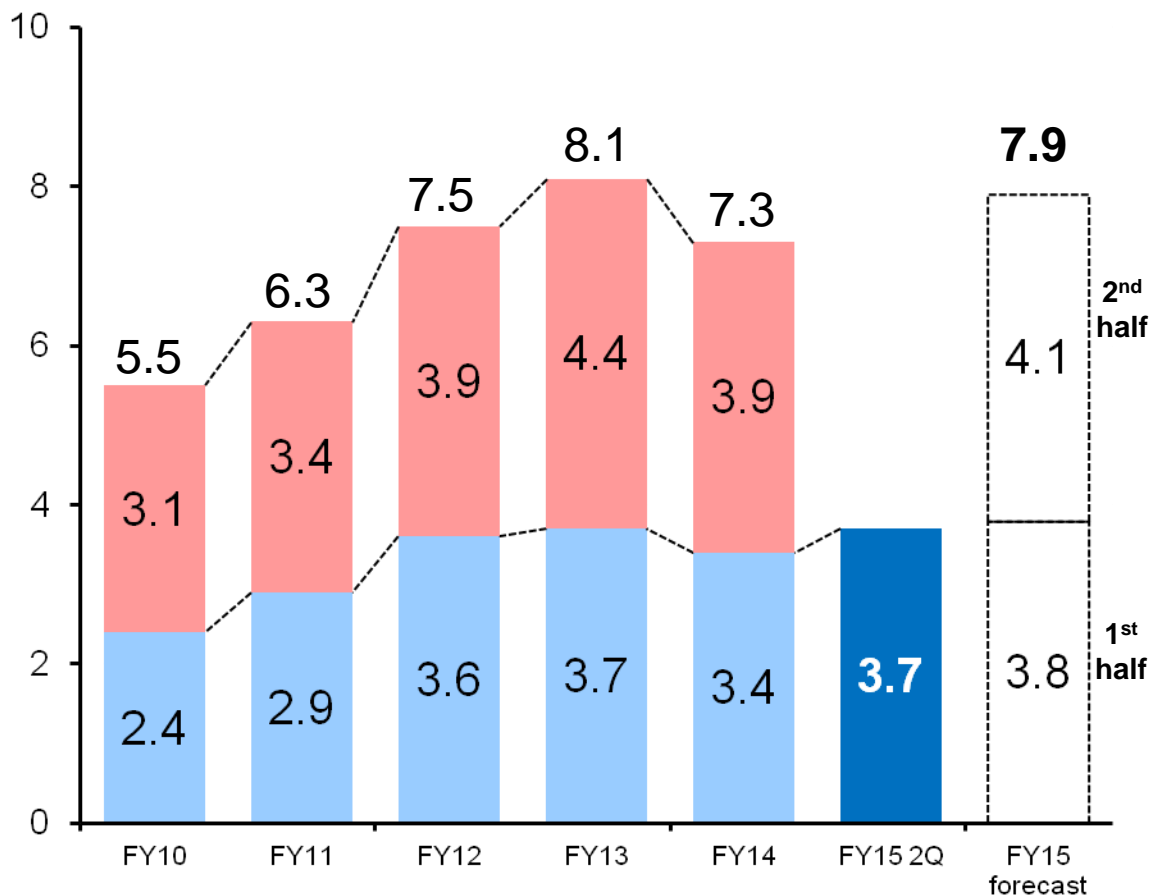


Reference

■ New drugs group

Uritos 【Overactive bladder】

Sales (unit : ¥billion)



■ Status in first half 2015

- **OAB market : expand 13%**
 ¥37.8bln (FY14 first half) ⇒ ¥42.6bln (FY15 first half) ※1
- **share of Uritos sales**
 10.3% (FY14 first half) ⇒ 9.6% (FY15 first half) ※2

■ effort for FY2015

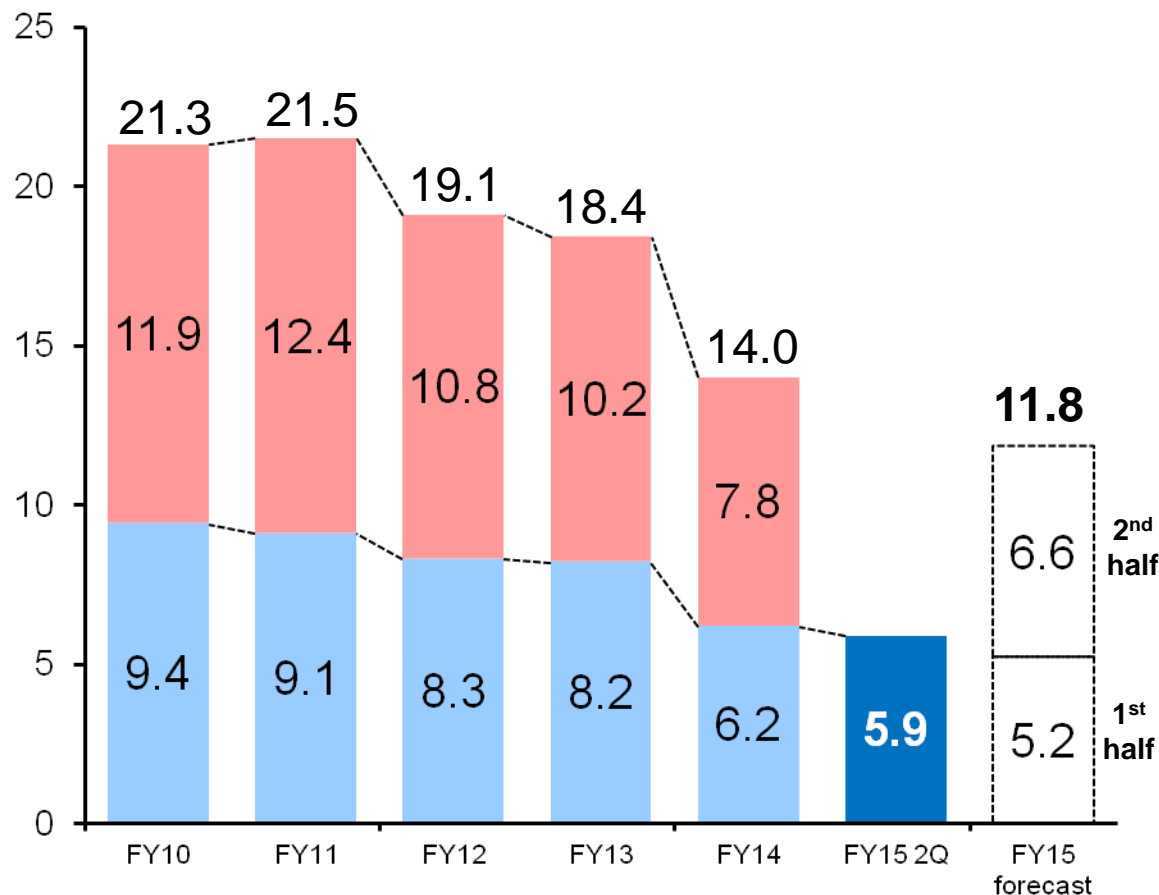
- **Uncovering potential markets**
 FY14 : consultation rate 30%
- **Pervading usability**
 prescriptions based on EBM (OAB patient with BPH ※3)

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 ※3 benign prostatic hypertrophy

Original products group

Mucodyne 【 Mucoregulating drug 】

Sales (unit : ¥billion)



■ Status in first half 2015

- **expectorant market: expand 2%**
 ¥17.7bln (FY14 first half) ⇒ ¥18.0bln (FY15 first half) ※1
- **share of Mucodyne sales in expectorant market**
 41.3% (FY14 first half) ⇒ 37.8% (FY15 first half) ※2
- **share of generic (Carbocisteine)**
 10.8% (FY14 first half) ⇒ 13.3% (FY15 first half) ※3

■ effort for FY2015

- **Maximize uptake and prescriptions of new formulation 「DS50%」**

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P&L Summary: Consolidated Results – (1)

(unit : ¥million)

	Sep/2014		Sep/2015			
	Actual	% Sales	Actual	% Sales	% Change	Change
Sales	51,112	100.0%	52,386	100.0%	+2.5%	+1,274
■ Ethical Drugs business	50,518	98.8%	51,783	98.8%	+2.5%	+1,264
◆ Sales of new Ethical Drugs	40,755	79.7%	42,229	80.6%	+3.6%	+1,473
○Japan	40,422	79.1%	41,634	79.5%	+3.0%	+1,211
○Overseas	332	0.6%	594	1.1%	+78.7%	+261
◆ Generic Drugs	7,790	15.2%	7,393	14.1%	-5.1%	-397
◆ Over-the-counter Drugs and Others	1,972	3.9%	2,160	4.1%	+9.5%	+188
■ Consumer Healthcare Business	593	1.2%	603	1.2%	+1.7%	+10

< Breakdown >

Year on Year

■ Sales ¥52,386mil (+¥1,274mil)

● Ethical drug sales in Japan
¥41,634mil (+¥1,211mil)

Sep/20134⇒Sep/2015(¥ billion)

• Kipres 17.4 ⇒ 18.8 (+1.4)
• Mucodyne 6.2 ⇒ 5.9 (-0.3)
• Pentasa 8.6 ⇒ 8.1 (-0.5)
• Uritos 3.4 ⇒ 3.7 (+3.0)
• Flutifom 0.9 ⇒ 3.0 (+2.1)

● Ethical drug sales overseas

¥594mil (+ ¥261mil)

• Gatifloxacin ¥0.1bln → 0.4bln (+ ¥0.3bln)

● Generic Drugs ¥7,393mil (- ¥397mil)

• increase of Health insurance pharmacy market's sales
• decrease of Contract manufacturing's sales

● Over-the-counter Drugs and Others
¥2,160mil (+ ¥188mil)

● Consumer Healthcare (skincare) Business
¥603mil (+ ¥10mil)

<Subsidiaries and Equity-method Affiliates>

Consolidated subsidiaries (8) :

- KYORIN Pharmaceutical Co., Ltd.
- Kyorin USA, Inc.
- ActivX Biosciences, Inc.
- Dr. Program Co., Ltd.
- KYORIN Pharmaceutical Facilities Co.,Ltd.
- Kyorin Europe GmbH
- KYORIN Rimedio Co., Ltd.
- KYORIN Medical Supply Co., Ltd.

Equity-Method Affiliates: •Nippon Rika Co., Ltd.

P&L Summary: Consolidated Results – (2)

(unit : ¥million)

	Sep/2014		Sep/2015			
	Actual	% Sales	Actual	% Sales	% Change	Change
Sales	51,112	100.0%	52,386	100.0%	+2.5%	+1,274
Cost of Sales	21,340	41.8%	21,561	41.2%	+1.0%	+220
Gross Profit	29,771	58.2%	30,825	58.8%	+3.5%	+1,053
SG&A (Incl. R&D expenses)	25,183 (6,674)	49.3% (13.1%)	26,726 (7,270)	51.0% (13.9%)	+6.1% (+8.9%)	+1,542 (+595)
Operating Income	4,587	9.0%	4,099	7.8%	-10.6%	-488
Non-Operating Income	315	0.6%	206	0.4%	-34.7%	-109
Non-Operating Expenses	5	0.0%	39	0.1%	+591.7%	+33
Ordinary Income	4,898	9.6%	4,266	8.1%	-12.9%	-631
Extraordinary Profits	29	0.1%	0	0.0%	-98.4%	-28
Extraordinary Losses	32	0.1%	107	0.2%	+232.0%	+74
Income before income taxes	4,894	9.6%	4,159	7.9%	-15.0%	-735
Corporate, inhabitants and enterprise taxes	1,692	3.3%	936	1.8%	-44.6%	-755
Tax adjustments	-292	-0.6%	255	0.5%	—	+548
Net Income	3,495	6.8%	2,967	5.7%	-15.1%	-528

< Breakdown >

- ◆ **Cost of Sales Ratio :**
 down 0.6 percentage points Y/Y (41.8%→41.2%)
 - Sales of main product increased
 - Sales of generic drugs decreased
- ◆ **R&D Ratio :**
 up 0.8 percentage points Y/Y (13.1%→13.9%)
 - * ¥6.7bln→¥7.3bln (+0.6bln)
 - cost of new WATARASE research center , progress of project
- ◆ **SG&A (exclude R&D) Expenses :**
 up 0.9 percentage Points Y/Y(36.2%→37.1%)
 - * ¥18.5bln→¥19.5bln (-¥1.0bln)
 - increase of patent royalty,sales costs,
- **Operating Income ¥4,099mil (- ¥488mil)**
 - * Operating Income margin decreased 1.2percentage points to 7.8%
- **Net Income ¥2,697mil (- ¥528mil)**
- **Dividend per share(interim dividend) ¥20.0**

BS Summary: Consolidated Results

(Units: ¥ million)	Mar/2015	
	Actual	%total
Current Assets	129,064	70.4%
Cash, deposits	30,652	
Notes and accounts receivable	47,007	
Mk securities	17,867	—
Inventory	25,929	
Other	7,607	
Fixed Assets	54,318	29.6%
Tangible assets	19,374	
Intangible assets	1,184	—
Investments	33,760	
Total Assets	183,383	100.0%

Sep/2015		
Actual	% total	change
124,080	66.1%	−4,984
45,043		
38,609		
6,286	—	—
27,101		
7,039		
63,649	33.9%	+9,330
23,535		
1,060	—	—
39,053		
187,729	100.0%	+4,346

Current Liabilities	27,773	15.1%
Notes payable	11,259	—
Other	16,513	
Non-Current Liabilities	7,009	3.8%
Total Liabilities	34,782	19.0%
Owner's Equity	140,518	76.6%
Other Comprehensive Income	8,082	4.4%
Unrealized holding gain (loss) on securities	7,798	
Foreign currency translation adjustments	168	—
	115	
Total Equity	148,600	81.0%
Total Liabilities and Equity	183,383	100.0%

27,591	14.7%	−181
10,980	—	—
16,611		
8,491	4.5%	+1,482
36,083	19.2%	+1,301
141,375	75.3%	+856
10,271	5.5%	+2,188
9,989		
183	—	—
98		
151,646	80.8%	+3,045
187,729	100.0%	+4,346

< Breakdown >

■ Current Asset : −4,984

- Cash, deposits (+14,390)
- Notes and accounts receivable (−8,398)
- Mk securities (−11,580)
- Inventory (+1,171)

■ Fixed Assets : +9,330

- Tangible Assets (+4,161)
- Intangible Assets (−124)
- Investments (+5293)

■ Current Liabilities : −181

- Notes Payable (−278)
- Other (+97)

■ Non-Current Liabilities : +1,482

Financial summary (Consolidated)

(unit : ¥million)

	Sep/2013	Sep/2014	Sep/2015
Sales (Exports)	50,851 (1,160)	51,112 (332)	52,386 (594)
Cost of Sales (cost of Sales Ratio)(%)	19,097 (37.6%)	21,340 (41.8%)	21,561 (41.2%)
SG&A Ratio to Sales (%)	25,541 (50.2%)	25,183 (49.3%)	26,726 (51.0%)
R&D Expenses Ratio to Sales (%)	6,119 (12.0%)	6,674 (13.1%)	7,270 (13.9%)
Operating Income Ratio to Sales (%)	6,213 (12.2%)	4,587 (9.0%)	4,099 (7.8%)
Ordinary Income Ratio to Sales (%)	6,531 (12.8%)	4,898 (9.6%)	4,266 (8.1%)
Net Income Ratio to Sales (%)	4,397 (8.6%)	3,495 (6.8%)	2,967 (5.7%)
EPS (¥)	¥58.85	¥46.78	¥40.10
Capital	700	700	700
Assets	155,840	164,354	187,729
Total Equity	130,098	139,037	151,646
BPS (¥)	¥1,741.24	¥1,860.90	¥2,047.91
ROE (%)	3.4%	2.5%	2.0%
Equity Ratio (%)	83.5%	84.6%	80.8%
Employees	2,481	2,482	2,448
Capital Expenditure	1,618	1,557	5,637
Depreciation Expense	1,460	1,462	1,658

Mar/2015	Mar/2016 (forecast)
113,121 (1,032)	120,200 (1,000)
46,598 (41.2%)	—
51,785 (45.8%)	—
13,514 (11.9%)	13,400 (11.1%)
14,737 (13.0%)	16,000 (13.3%)
15,490 (13.7%)	16,300 (13.6%)
12,064 (10.7%)	11,500 (9.6%)
¥161.63	¥155.51
700	—
183,383	—
148,600	—
¥2,009.45	—
8.4%	—
81.0%	—
2,445	—
2,655	8,700
3,053	3,800

Segment information for the Second Quarter Ended Sep 30, 2015

Sales, Profit or Loss of each report segment

	Sales	change Y/Y	Profit	change Y/Y
Net Sales (total)	52.4	+1.3	4.1	-0.5
Ethical drugs business	51.8	+1.3	4.0	-0.5
◆Sales of new ethical drugs	42.2	+1.4		
○Japan	41.6	+1.2		
○Overseas	0.6	+0.3		
◆Generic drugs	7.4	-0.4		
◆Over-the-counter drugs	2.2	+0.2		
Healthcare(Skincare) business	0.6	0	0	0
Amount of adjustment	—	—	0.1	0

(Note) The Company is applying the Revised Accounting Standard for Disclosures about Segments of an Enterprise and Related Information and the Guidance on the Accounting Standard for Disclosures about Segments of an Enterprise and Related Information. As a result, the reported segments are the Ethical Drugs Business and the Consumer Healthcare Business.

P&L summary : KYORIN pharmaceutical (Non-consolidated)-(1)

(unit : ¥million)

< Breakdown >

Year on Year

	Sep/2014		Sep/2015			
	Actual	% Sales	Actual	% Sales	% Change	Change
Sales	43,922	100.0%	46,157	100.0%	+5.1%	+2,234
■ Ethical Drugs business	43,922	100.0%	46,157	100.0%	+5.1%	+2,234
◆ Sales of new Ethical Drugs	39,353	89.6%	41,108	89.1%	+4.5%	+1,754
○ Japan	39,107	89.0%	40,604	88.0%	+3.8%	+1,496
○ Overseas	246	0.6%	504	1.1%	+104.9%	+258
◆ Generic Drugs	3,120	7.1%	3,283	7.1%	+5.2%	+162
◆ Over-the-counter Drugs and Others	1,448	3.3%	1,765	3.8%	+21.9%	+317

■ Sales	¥46,157mil	(+¥2,234mil)
● Ethical drug sales in Japan	¥40,604mil	(+¥1,496mil)
Sep/2014⇒Sep/2015(¥ billion)		
・ Kipres	17.4 ⇒ 18.8	(+1.4)
・ Mucodyne	6.2 ⇒ 5.9	(-0.3)
・ Pentasa	8.6 ⇒ 8.1	(-0.5)
・ Uritos	3.4 ⇒ 3.7	(+0.3)
・ Flutiform	0.9 ⇒ 3.0	(+2.1)
● Ethical drug sales overseas	¥504mil	(+ ¥258mil)
・ Gatifloxacin	¥0.1bln → ¥0.4bln	(+ ¥0.3bln)
● Generic Drugs	¥3,283mil	(+ ¥162mil)
● Over-the-counter Drugs and Others	¥1,765mil	(+ ¥317mil)
・ milton	¥1.0bln → ¥1.0bln	(0)
・ Rubysta	¥0.2bln → ¥0.3bln	(+ ¥0.1bln)

P&L summary : KYORIN pharmaceutical (Non-consolidated)-(2)

(unit : ¥million)

< Breakdown >

	Sep/2014		Sep/2015			
	Actual	% Sales	Actual	% Sales	% Change	Change
Sales	43,922	100.0%	46,157	100.0%	+5.1%	+2,234
Cost of Sales	17,354	39.5%	18,358	39.8%	+5.8%	+1,003
Gross Profit	26,567	60.5%	27,799	60.2%	+4.6%	+1,231
SG&A (R&D Expenses)	23,069 (6,334)	52.5% (14.4%)	24,637 (6,903)	53.4% (15.0%)	+6.8% (+9.0%)	+1,567 (+569)
Operating Income	3,498	8.0%	3,161	6.8%	-9.6%	-336
Non-Operating Income	459	1.0%	306	0.7%	-33.3%	-153
Non-operating Expenses	0	0.0%	0	0.0%	+348.2%	0
Ordinary Income	3,957	9.0%	3,468	7.5%	-12.4%	-489
Extraordinary Profits	29	0.1%	-	-%	-%	-29
Extraordinary Losses	7	0.0%	45	0.1%	+538.5%	+38
Income before income taxes	3,979	9.1%	3,422	7.4%	-14.0%	-557
Corporate, inhabitants and enterprise taxes	1,361	3.1%	701	1.5%	-48.5%	-659
Tax adjustments	-321	-0.7%	239	0.5%	-174.5%	+561
Net Income	2,940	6.7%	2,481	5.4%	-15.6%	-459

◆ **Cost of Sales Ratio :**
up 0.3 percentage points Y/Y (39.5%→39.8%)

◆ **R&D Ratio : up 0.6percentage points Y/Y(14.4%→15.0%)**
 * ¥6.3bln→¥6.9bln(+¥0.6 bln)
 ・ cost of new WATARASE research center , progress of project

◆ **SG&A (exclude R&D) expenses :**
UP 0.3 percentage points Y/Y (38.1%→38.4%)

■ **Operating Income ¥3,161mil (-¥336mil)**

* Operating Income margin decreased 1.2 percentage points to 6.8%

■ **Net Income ¥2,481mil (- ¥459mil)**

BS Summary: KYORIN Pharmaceutical (Non-consolidated)

(unit : ¥million)

	Mar/2015	
	Actual	% total
Current Assets	97,822	68.4%
Cash, deposits	14,587	
Accounts receivable	43,220	
Mk securities	12,804	—
Inventory	21,763	
Other	5,447	
Fixed Assets	45,145	31.6%
Tangible assets	12,324	
Intangible assets	376	—
Investments	32,444	
Total Assets	142,967	100.0%

Current Liabilities	20,958	14.7%
Notes Payable	8,323	—
Other	12,635	
Non-Current Liabilities	3,762	2.6%
Total Liabilities	24,720	17.3%
Owner's Equity	110,534	77.3%
Valuation and translation adjustments	7,712	5.4%
Total Equity	118,246	82.7%
Total Liabilities and Equity	142,967	100.0%

Sep/2015		
Actual	% total	change
92,433	63.1%	−5,389
22,937		
35,381		
6,003	—	—
22,443		
5,667		
54,025	36.9%	+8,880
15,881		
331	—	—
37,812		
146,458	100.0%	+3,491

20,899	14.3%	−58
7,893		
13,005	—	—
5,003	3.4%	+1,240
25,902	17.7%	+1,182
110,639	75.5%	+104
9,916	6.8%	+2,203
120,555	82.3%	+2,308
146,458	100.0%	+3,491

< Breakdown >

- Current Assets : −5,389mil
 - Cash, deposits (+¥8,350mil)
 - Accounts receivable (−¥7,838mil)
 - Mk securities (−¥6,801mil)
 - Inventory (+¥679mil)
- Fixed Assets : + ¥8,880mil
 - Tangible Assets (+¥3,557mil)
 - Intangible Assets (−¥45mil)
 - Investments (+¥5,367mil)
- Current Liabilities : − ¥58mil
 - Notes Payable (−¥429mil)
 - Other (+¥370mil)
- Non-Current Liabilities : +¥1,240mil

Financial Summary: KYORIN Pharmaceutical (Non-consolidated)



(unit : ¥million)

	Sep/2013	Sep/2014	Sep/2015
Sales (Exports)	44,933 (1,097)	43,922 (246)	46,157 (504)
Cost of Sales (cost of sales ratio) %	15,609 (34.7%)	17,354 (39.5%)	18,358 (39.8%)
SG&A Ratio to Sales (%)	23,748 (52.9%)	23,069 (52.5%)	24,637 (53.4%)
R&D Expenses Ratio to Sales (%)	5,848 (13.0%)	6,334 (14.4%)	6,903 (15.0%)
Operating Income Ratio to Sales (%)	5,575 (12.4%)	3,498 (8.0%)	3,161 (6.8%)
Ordinary Income Ratio to Sales (%)	6,087 (13.5%)	3,957 (9.0%)	3,468 (7.5%)
Net Income Ratio to Sales (%)	4,261 (9.5%)	2,940 (6.7%)	2,481 (5.4%)
EPS (¥)	¥57.38	¥39.60	¥33.41
Capital	4,317	4,317	4,317
Assets	122,396	126,945	146,458
Total Equity	103,608	110,288	120,555
BPS (¥)	¥1,395.06	¥1,485.00	¥1,623.24
ROE (%)	4.1%	2.7%	2.1%
Equity Ratio (%)	84.7%	86.9%	82.3%
Employees	1,797	1,801	1,762
Capital Expenditure	929	635	4,435
Depreciation Expense	807	814	961

Mar/2015	Mar/2016 (forecast)
98,452 (840)	105,300 (700)
38,951 (39.6%)	—
47,349 (48.1%)	—
12,843 (13.0%)	12,700 (12.1%)
12,151 (12.3%)	13,300 (12.6%)
13,115 (13.3%)	13,800 (13.1%)
10,412 (10.6%)	10,000 (9.5%)
¥140.20	—
4,317	—
142,967	—
118,246	—
¥1,592.16	—
9.1%	—
82.7%	—
1,771	—
1,125	6,100
1,667	2,200

Consolidated Financial Results for the Second Quarter and full year forecast

(unit : ¥million)

	Sep/2014	Sep/2015	Change	% Y/Y
Sales	51,112	52,386	+1,274	+2.5%
■ Ethical Drugs business	50,518	51,783	+1,264	+2.5%
◆ Sales of new Ethical Drugs	40,755	42,229	+1,473	+3.6%
○ Japan	40,422	41,634	+1,211	+3.0%
○ Overseas	332	594	+261	+78.7%
◆ Generic Drugs	7,790	7,393	-397	-5.1%
◆ Over-the-counter Drugs and Others	1,972	2,160	+188	+9.5%
■ Consumer Healthcare Business	593	603	+10	+1.7%
Operating Income	4,587	4,099	-488	-10.6%
Ordinary Income	4,898	4,266	-631	-12.9%
Net Income	3,495	2,967	-528	-15.1%

	Mar/2015	Mar/2016 (forecast)
	113,121	120,200
	111,771	118,600
	92,111	95,700
	91,079	94,700
	1,032	1,000
	15,477	18,200
	4,183	4,500
	1,349	1,600
	14,737	16,000
	15,490	16,300
	12,064	11,500

Actual and Forecast of Main Subsidiary Companies

(unit : ¥billion)

KYORIN pharmaceutical	Sep/2014	Sep/2015
Sales	43.9	46.2
Operating Income	3.5	3.2
Net Income	2.9	2.5

Mar/2015	Mar/2016 (forecast)
98.5	105.3
12.2	13.3
10.4	10.0

KYORIN Rimedio	Sep/2014	Sep/2015
Sales	8.0	7.4
Operating Income	0.9	0.6
Net Income	0.6	0.4

Mar/2015	Mar/2015 (forecast)
16.4	18.5
2.1	2.3
1.5	1.6

Dr. Program	Sep/2014	Sep/2015
Sales	0.6	0.6
Operating Income	0	0
Net Income	0	0

Mar/2015	Mar/2015 (forecast)
1.4	1.6
0	0
0	0

Main Product Sales Update

(unit : ¥billion)

Product name		Sep/2012	Sep/2013	Sep/2014	Sep/2015		Mar/2015	Mar/2016 (forecast)
					Actual	% change		
Sales of new ethical drugs (Japan)	Kipres (LT receptor antagonist)	16.3	17.1	17.4	188	+7.9%	41.2	41.8
	Mucodyne (Mucoregulant)	8.3	8.2	6.2	59	-3.6%	14.0	11.8
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	9.0	9.4	8.6	81	-5.9%	17.2	17.1
	Uritos (Kyorin) (Therapeutic agent for overactive bladder)	3.6	3.7	3.4	37	+9.3%	7.3	7.9
	Flutiform (Combination drug for asthma treatment)	—	—	0.9	30	+216.2%	3.6	10.3
Sales of new ethical drugs (over seas)	Gatifloxacin (Bulk · Royalty)	0.9	1.0	0.1	0.4	+178.7%	0.6	0.4
Over-the-counter drugs	Milton (Disinfectant)	1.0	1.0	1.0	1.0	+8.5%	2.0	2.0

R&D Expenses, Capex & Depreciation

(unit : ¥million)

	Sep/2012	Sep/2013	Sep/2014	Sep/2015	change	Mar/2015	Mar/2016 (forecast)
R&D expenses	4,892	6,119	6,674	7,270	+8.9%	13,514	13,400
Capital expenditure	1,181	1,618	1,557	5,637	+262.1%	2,655	8,700
Depreciation expense	1,119	1,460	1,462	1,658	+13.4%	3,053	3,800

<Capital expenditure (Actual/Forecast)>

(unit : ¥billion)

	Sep/2014	Sep/2015	Mar/2015	Mar/2016 (forecast)
Plant facilities	0.9	1.3	1.5	2.9
Equipment for control, sales activities	0.2	0.1	0.3	0.8
Equipment for research	0.4	4.2	0.8	5.0

Main R&D Activities -1 (as of Nov 5 2015)

Ph III ~ Application submitted

※Changes from the previous announcement(July 30 2015)

Stage		Compound/ Code	Therapy area/Action	Origin	Features	Comments
Japan	Overseas					
PhIII (13年8月)	(Europe) AstraZeneca :Launched (1/2015) (US) AstraZeneca : PhIII	KRP-AB1102F (Fixed dose combination inhaled drug)	Chronic Obstructive Pulmonary Disease (COPD)	Almirall	Combination of acclidinium bromide with the long acting beta agonist formoterol : This combination is aimed at providing higher efficacy than each component alone,as well as the improved convenience of having the two products in the same easy to use inhalation device.This is currently in phase III clinical development.	
PhIII (1/2015)	Ph II clinical trial end Merck & Co.,	KRP-114V	Overactive bladder	Merck & Co.,	KRP-114V is expected to improve urinary frequency through stimulation of the beta 3 receptor in bladder which improves bladder muscle relaxation.	License agreement with Merck & Co., Inc.,(7/2014)
PhIII (4/2015)		KRP-AM1977X (Oral agent)	New quinolone synthetic antibacterial agent	In-house	①Superior ability to combat drug-resistant gram- positive bacteria (incl. MRSA) ②Outstanding ADME (oral absorption, tissue migration) ③High degree of safety expected since safety hurdles cleared prior to clinical trials	

for reference

Stage	Compound/ Code	Therapy area/Action	Features	Comments
※Application submitted by MSD K.K.	Desloratadine	allergic rhinitis, hives, itching resulting from skin diseases (eczema/dermatitis, pruritus cutaneous)	second generation histamine H1-receptor antagonist	Co-Marketing Agreement for Japan with MSD K.K. affiliate (11/2014)

Main R&D Activities -2 (as of Nov 5 2015)

POC Project (Ph I ~ Ph II)

※Changes from the previous announcement(July 30 2015)

Stage		Compound/ Code	Therapy area/Action	Origin	Features	Comments
Japan	Overseas					
※Ph II (8/2015)	Ph III Merz	KRP-209	Tinnitus	Merz	KRP-209 (Neramexane) is expected to improve the patients' annoyance and difficulties in their life caused by tinnitus, mainly through its two pharmacological properties: 1) NMDA antagonistic activity and 2) Nicotinic acetylcholine antagonistic activity	License agreement with Merz (11/2009) Merz:Ph I clinical trial of Japanese patients in US completed (3/2010)
Ph II (3/2013) ※discontinued	License out : Novartis Ph II (POC) (12/2010)	KRP-203	Transplantation, autoimmune diseases, and IBD	In-house	An immunosuppressant with a novel mechanism called an S1P-agonist. It may have a better safety profile than previous ones as well as an excellent effect under concomitant use with other types of immunomodulator.	License agreement with Novartis (2/2006) New license agreement IBD (11/2010) ※Discontinued development of IBD for KRP-203 in Japan. Novartis has decided to proceed with development of KRP-203 for GvHD.
Ph II (6/2014)		KRP-AM1977Y (Injection)	New quinolone synthetic antibacterial agent	In-house	①Superior ability to combat drug-resistant gram-positive bacteria (incl. MRSA) ②Outstanding ADME (oral absorption, tissue migration) ③High degree of safety expected since safety hurdles cleared prior to clinical trials	
Ph I , II (7/2015)	(US) Momotaro-Gene prostate cancer (5/2014)	Ad-SGE-REIC	malignant pleural mesothelioma	Okayama University	A gene-therapy product using a novel tumor suppressor gene of reduced expression in immortalized cells/ Dickkopf-3 (REIC/Dkk-3), which was discovered by researchers from Okayama University, as a therapeutic gene. It is expected to have direct effect on primary tumor lesions and indirect effect on metastatic tumor lesions as a gene-therapy product that simultaneously induces tumor cell-selective apoptosis and the activation of antitumor immunity respectively.	Adopted to Next generation Technology Transfer Program (NexTEP) (6/2014)

- 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.