

# **Financial Results for Fiscal 2016**

**May 12 , 2017**  
**KYORIN Holdings, Inc.**  
**President Minoru Hogawa**



## ➤ **Outline of Consolidated Financial Results**

- Trends of mainstay products

## ➤ **Consolidated Financial Results and Forecast**

## ➤ **Status of development pipeline**

## ➤ **Initiatives toward realization of the long-term vision “HOPE 100”**

- Progress of Medium-Term Business Plan “HOPE 100-Stage 2-”  
(Fiscal 2016～2019)

# Outline of Consolidated Financial Results

# Outline of Consolidated Financial Results for Fiscal 2016

(unit : ¥billion)

	FY2015	FY2016	Change	Change (%)	Change (revised forecast)	Change (original forecast)
Net Sales	119.5	<b>115.4</b>	-4.1	-3.4	+0.4	-4.6
Operating Income	19.6	<b>10.4</b>	-9.2	-47.0	+0.4	-4.1
Ordinary Income	20.0	<b>10.9</b>	-9.1	-45.6	+0.5	-4.0
Net Income	13.6	<b>7.3</b>	-6.3	-46.4	+0.7	-3.4

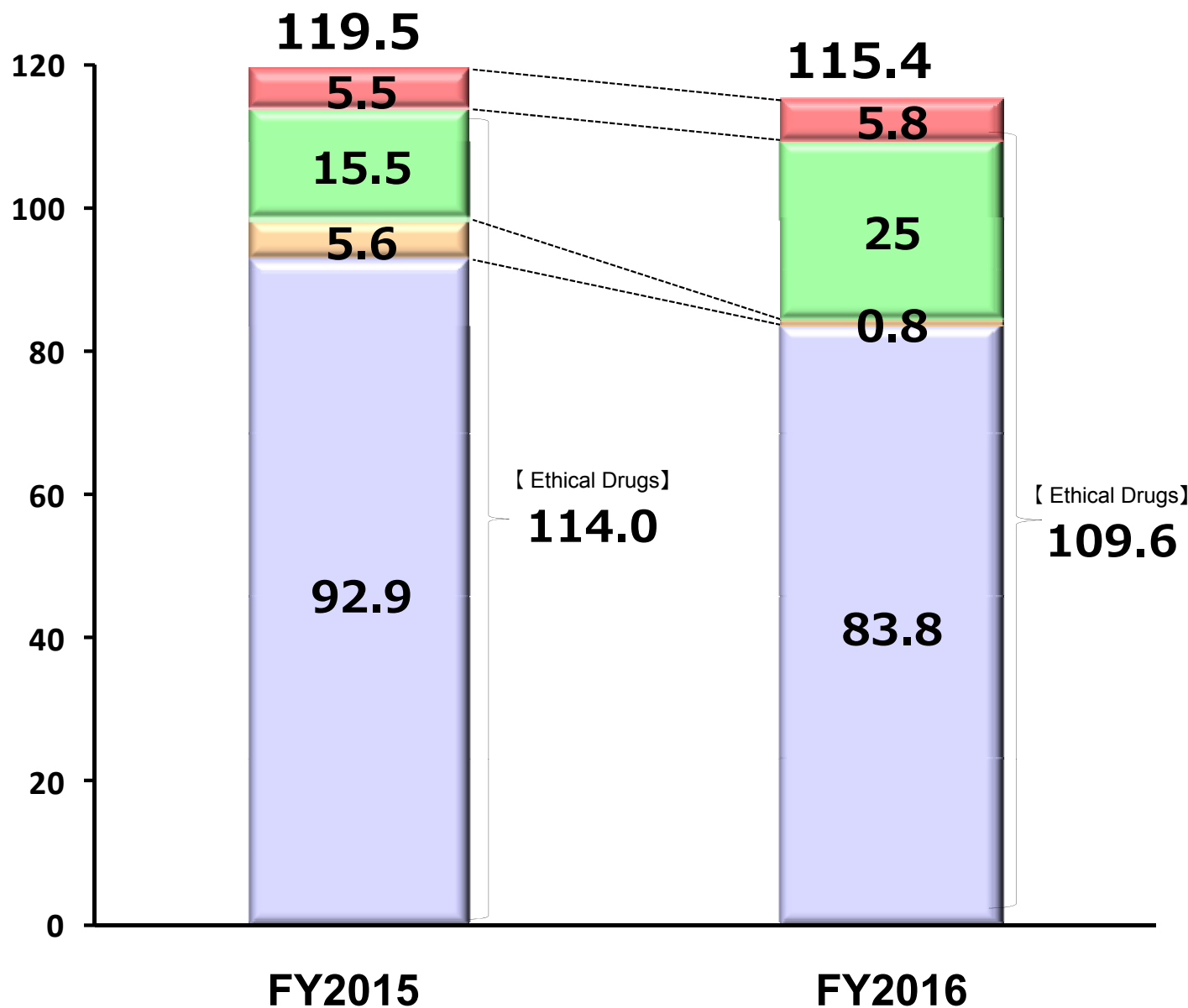
# Breakdown of Gain and Loss

(unit : ¥billion)

			FY2015	FY2016	Change	Change (%)	Change (revised forecast)	Change (original forecast)
<b>Net Sales</b>			119.5	<b>115.4</b>	<b>-4.1</b>	<b>-3.4</b>	+0.4	-4.6
			114.0	109.6	-4.4	-3.9	+0.5	-4.4
Ethical drugs business	Sales of new ethical drugs		98.5	84.5	-14.0	-14.2	-0.4	-7.9
		Japan	92.9	83.8	-9.1	-9.8	-0.2	-4.7
		Overseas	5.6	0.8	-4.8	-86.3	0	-3.0
	Generic drugs		15.5	25.0	+9.5	+61.8	+0.9	+3.5
Healthcare Business			5.5	5.8	+0.3	+5.4	-0.1	-0.2
<b>Cost of Sales</b>			47.4	<b>50.8</b>	<b>+3.4</b>	<b>+7.4</b>	-	-
<b>SG&amp;A</b>			52.5	<b>54.1</b>	<b>+1.6</b>	<b>+3.1</b>	-	-
<b>Operating Income</b>			19.6	<b>10.4</b>	<b>-9.2</b>	<b>-47.0</b>	+0.4	-4.1
<b>Ordinary Income</b>			20.0	<b>10.9</b>	<b>-9.1</b>	<b>-45.6</b>	+0.5	-4.0
<b>Net Income</b>			13.6	<b>7.3</b>	<b>-6.3</b>	<b>-46.4</b>	+0.7	-3.4

# Highlights of Business Performance ① (Sales)

( Units: ¥ billion )



【 Net Sales ¥-4.1billion】

**Healthcare Business +0.3**

- Growth of RUBYSTA and Milton

【 Ethical Drugs Sales ¥-4.4billion】

**Generic drugs +9.5**

- Sales of the MONTELUKAST"AG" for KIPRES and The other generic drugs increased.

**Ethical drug sales overseas -4.8**

- Decrease of upfront payment income for FPR-agonists(12/2015)

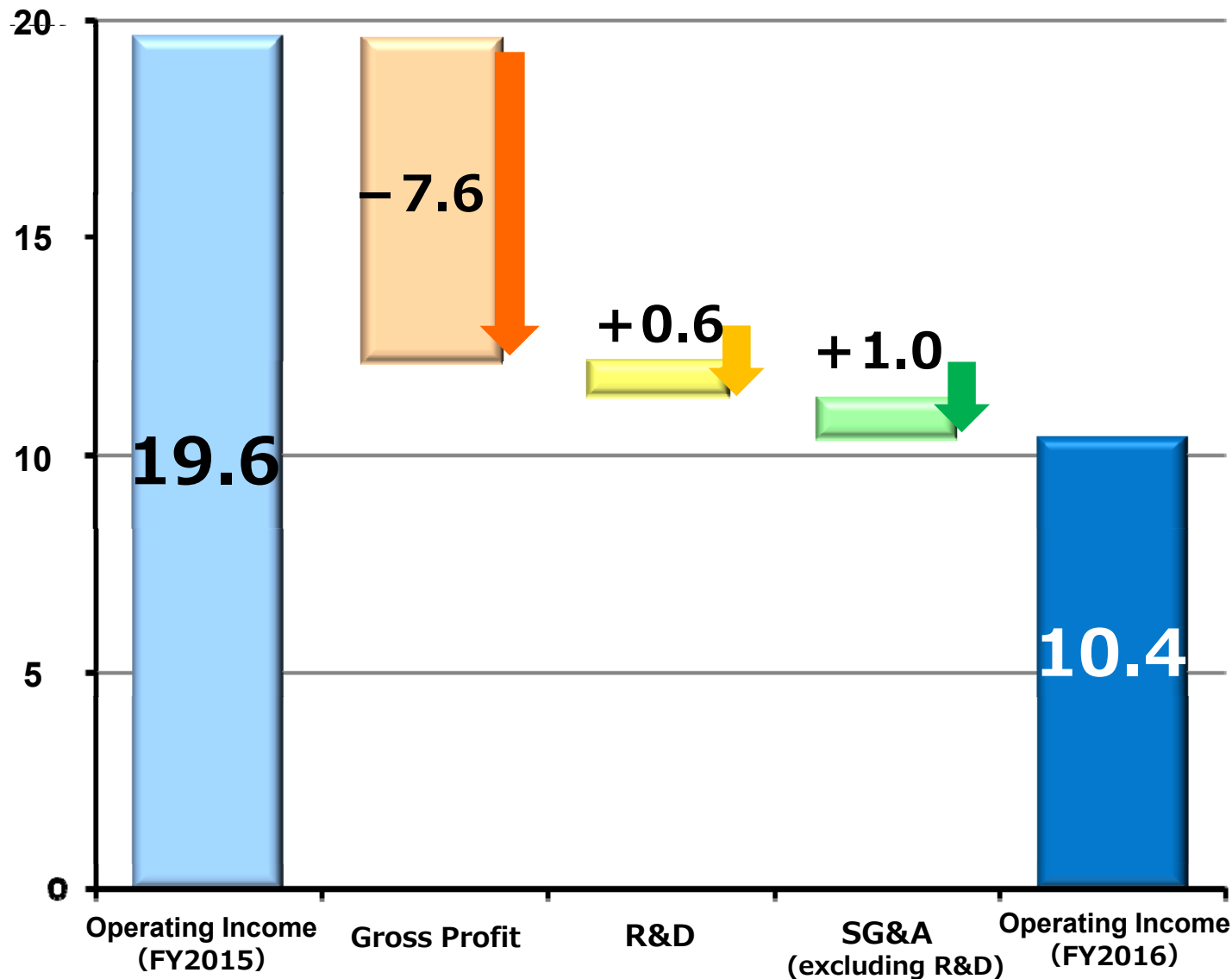
**Ethical drug sales in Japan -9.1**

- Increase of the flutiform sales / Launch of the DESALEX
- Drug price revisions/Decline in prescriptions of long-listed drugs / Decrease of the Kipres sales

# Highlights of Business Performance ② (Income)

( Units: ¥ billion )

**【Operating Income ¥ – 9.2billion】**



## Gross Profit decreased

**Net Sales : decreased ¥4.1billion year on year**

- Sales of new ethical drugs decreased
- Sales of generic drugs increased

**Cost of sales ratio : Increased 4.5% year on year**

- Drug price revisions
- Decrease of upfront payment income for in-licensed product overseas

## R&D expenses increased

- progress of development project (KRP-AM1977X, KRP-114V)
- ¥13.0billion (FY2015)  
⇒ ¥13.6billion (FY2016)

## SG&A(excluding R&D) increased

- Increase of sales and general costs  
¥39.5billion (FY2015)  
⇒ ¥40.5billion (FY2016)

# Highlights of Business Performance ③



(Change : original forecast) 健康はキョーリンの願いです。

( Units: ¥ billion )

	FY2015	FY2016	Change	Change (%)	Change (revised forecast)	Change (original forecast)
<b>Net Sales</b>	119.5	<b>115.4</b>	<b>-4.1</b>	<b>-3.4</b>	+0.4	<b>-4.6</b>
	114.0	109.6	-4.4	-3.9	+0.5	-4.4
Ethical drugs business	Sales of new ethical drugs	98.5	-14.0	-14.2	-0.4	-7.9
	Japan	92.9	-9.1	-9.8	-0.2	<b>-4.7</b>
	Overseas	5.6	0.8	-4.8	-86.3	<b>-3.0</b>
	Generic drugs	15.5	25.0	+9.5	+61.8	+0.9
Healthcare Business	5.5	5.8	+0.3	+5.4	-0.1	-0.2
<b>Cost of Sales</b>	47.4	<b>50.8</b>	<b>+3.4</b>	<b>+7.4</b>	-	-
<b>SG&amp;A</b>	52.5	<b>54.1</b>	<b>+1.6</b>	<b>+3.1</b>	-	-
<b>Operating Income</b>	19.6	<b>10.4</b>	<b>-9.2</b>	<b>-47.0</b>	+0.4	<b>-4.1</b>
<b>Ordinary Income</b>	20.0	<b>10.9</b>	<b>-9.1</b>	<b>-45.6</b>	+0.5	-4.0
<b>Net Income</b>	13.6	<b>7.3</b>	<b>-6.3</b>	<b>-46.4</b>	+0.7	<b>-3.4</b>

## [Explanation of Variances (Change : original forecast) ]

**Net Sales** : In new pharmaceutical products in Japan, sales of Flutiform and Mucodyne less than initially forecast and, in new pharmaceutical products overseas, upfront payment income relating to an in-licensed product postponed . Meanwhile, in generic drugs, sales of the AG of Montelukast (KIPRES) are exceeded the initial forecast.

**Extraordinary losses** : Expenses of around 1,000 million yen related to the settlement of a lawsuit for violation in connection with an in-licensed product (Gatifloxacin eyedrops) were recorded as an extraordinary loss.



# Mainstay Product Sales

( Units: ¥ billion )

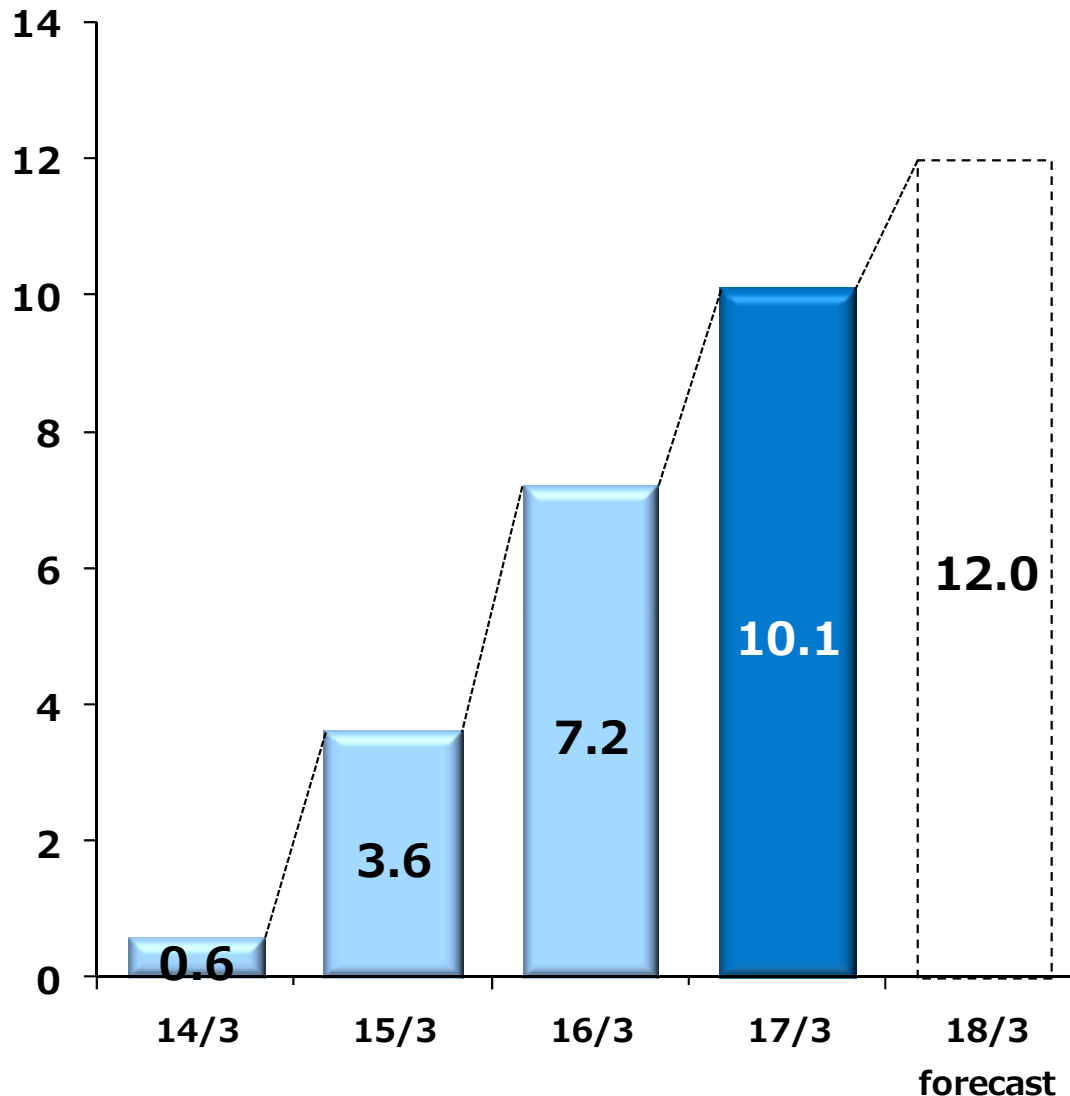
	FY2015	FY2016	Change	Change(%)	Change (revised forecast)	Change (original forecast)
<b>Flutiform</b> (Combination drug for asthma treatment)	7.2	<b>10.1</b>	+2.9	+39.0	0	-2.8
<b>Uritos</b> (Overactive bladder)	7.5	<b>7.5</b>	0	+0.1	-0.1	-0.3
<b>Desalex</b> (Antiallergic Agent)	0	<b>1.0</b>	+1.0	-	-0.9	-0.9
<b>Kipres</b> (LT receptor antagonist)	44.1	<b>32.7</b>	-11.4	-25.9	+0.8	-0.6
<b>For children</b>	15.4	<b>14.9</b>	-0.5	-3.3	+0.6	+0.6
<b>Pentasa</b> (Ulcerative colitis and Crohn's disease treatment)	16.1	<b>15.5</b>	-0.6	-3.9	0	-0.3
<b>Mucodyne</b> (Mucoregulant)	13.0	<b>9.9</b>	-3.1	-24.1	+0.2	-0.9
<b>MONTELUKAST Tablets“KM”※</b>	0	<b>8.2</b>	+8.2	-	+1.1	+4.1

# Trends of mainstay products

# ■ New drugs group

## Flutiform 【Anti-asthmatic】

( Units: ¥ billion )



### ■ status of FY2016

#### ● ICS/LABA market : expand 5.0%

¥108.2bln (FY2015) ⇒ ¥113.6 (FY2016) ※1

#### ● share of Flutiform sales

7.4% (FY2015) ⇒ 9.7% (FY2016) ※2

price revision rate ▲0.2%

### ■ effort for FY2017

#### ● Emphasize the characteristics of Flutiform

(Evidence-based stimulation of prescriptions)

- Low spray velocity
- The agent nicely penetrates and reaches the peripheral airways.

※1,2 (Source: Copyright 2016 IMS JAPAN IMS -JPM. Unauthorized copying prohibited )

## ■ New drugs group

# Desalex (Antiallergic Agent)

- Launch : Nov. 2016
- Sales : ¥1.0 billion (FY2016 sales)
- Sales forecast : ¥3.5 billion (FY2017 sales)



Promoted co-promotion with Kaken Pharmaceutical Co., Ltd. in dermatology area

### ● Improve the visibility of the product:

#### Spread the understanding on its effects and usability

- Has a high affinity for histamine H1 receptors and reliably exhibits an effect
- Half-life is long, and a single daily dose suppresses symptoms for a long time
- Fit patients' lifestyles because it is non-drowsy and unaffected by food

### ● Increase prescriptions

- Suggest that the drug should be prescribed for patients in whom it could be used for less than the 14-day prescription restriction

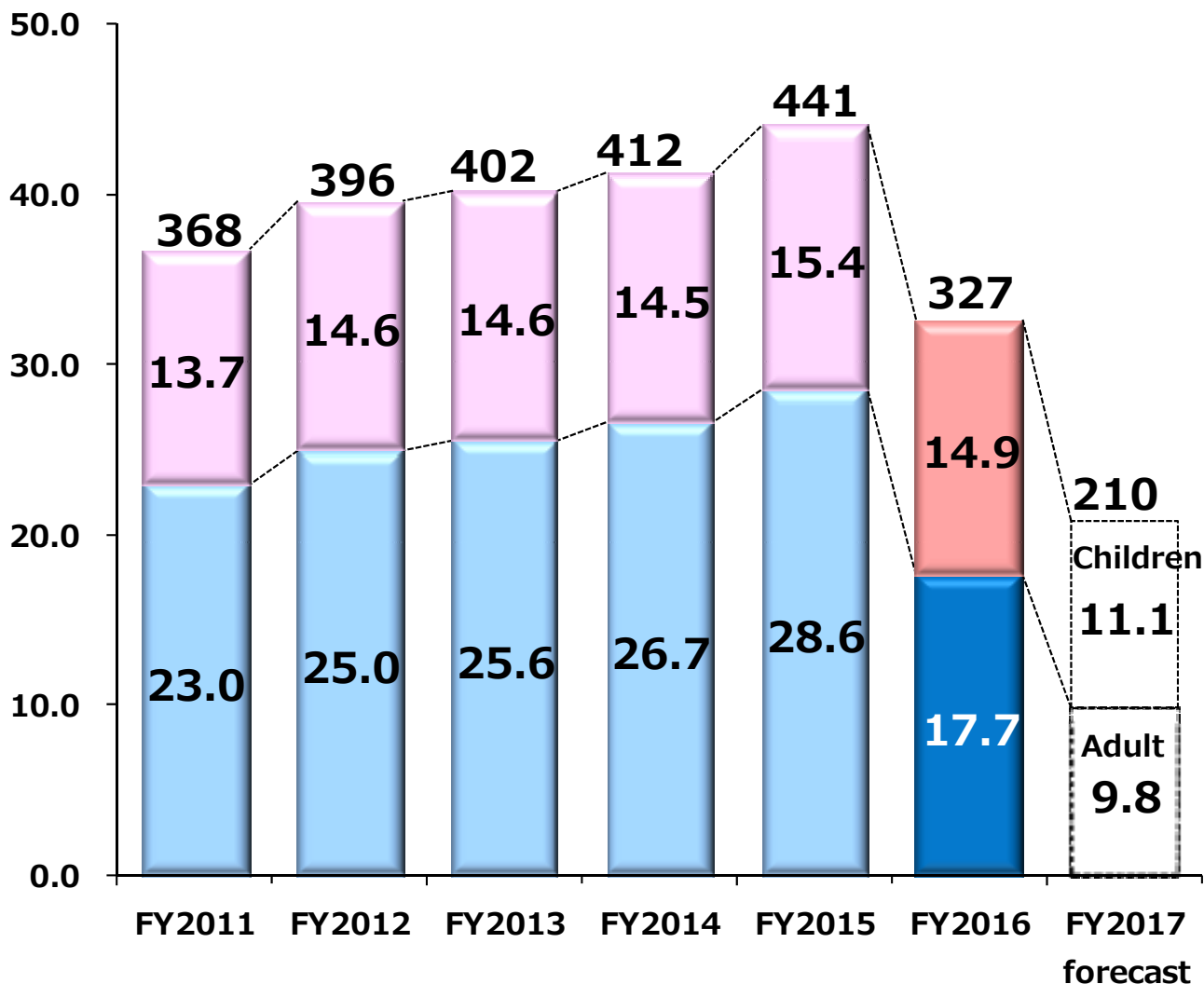
**Aim for dramatic market penetration after the lifting of prescription limitations**

(The prescription restriction will be lifted in December 2017)

# Original products group

## Kipres 【Bronchial asthma and allergic rhinitis treatment】

( Units: ¥ billion )



### status of FY2016

#### ●LT antagonists market : shrink 14.4%

¥ 132.2 (FY2015) ⇒ ¥113.2 (FY2016) ※1

#### ●share of Kipres sales

38.6% (FY2015) ⇒ 33.9% (FY2016) ※2

price revision rate ▲8.3%

### effort for FY2017

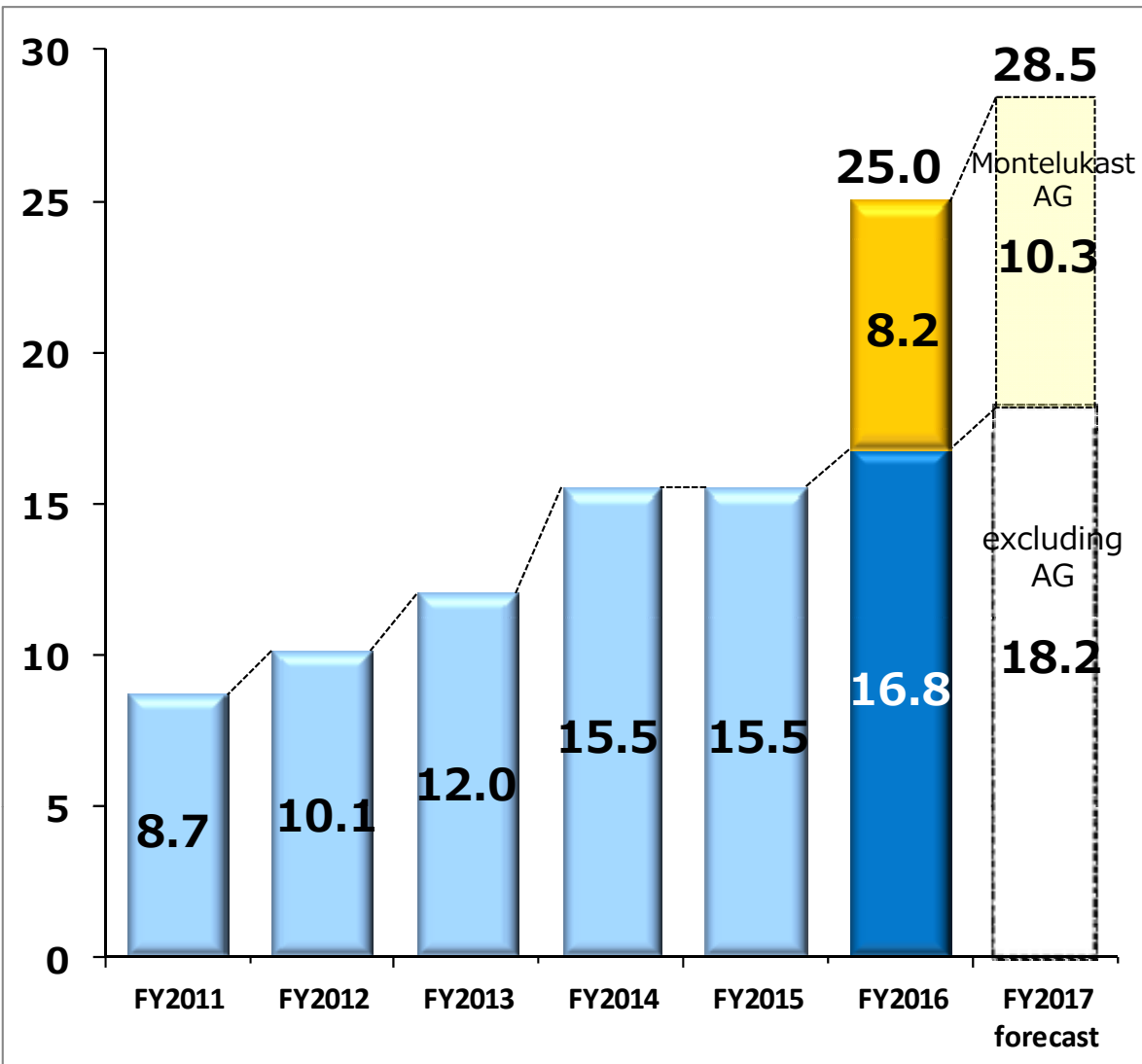
●Continuously provide accurate information to doctors prescribing the drug

●Promote it with drugs such as Flutiform and Desalex in the category of asthma and rhinitis

※1,2 ( Source: Copyright 2016 IMS JAPAN IMS -JPM. Unauthorized copying prohibited )

# ■ Status of Generic Drugs

( Units: ¥ billion )



## ■ status of FY2016

- Launch of an authorized generic drug (Sep. 2016)
- Turnover increase rate, excluding AG : +8.5%
  - ・ Increase of Health insurance pharmacy market's sales, contract manufacturing's sales
  - ・ Launched 4 components , 11 products in FY2016

## ■ effort for FY2017

- **Actions for an authorized generic drug (AG)**
  - ・ Maintain a high share of Montelukast AG in the GE market
  - ・ Consider acquiring new AGs
- **Expand sales of strategic products and Supplementary Items**
  - ・ 2016 June supplementary Item = Aripiprazole telmisartan etc.
- **Takaoka Drug Discovery Laboratory**  
( July of 2017 Start of operations )
  - ・ Aim to strengthen product development capabilities and increase the number of product items developed by our company
  - ・ Target : 20 or more development products per year



# **Consolidated Financial Results and Forecast**



# Consolidated Financial Results Forecast for the Year Ending March 31, 2018

( Units: ¥ billion )

			FY2016	FY2017 (forecast)	Y/Y	
					Change	Change(%)
<b>Net sales</b>			115.4	<b>113.4</b>	-2.0	-1.7
			109.6	107.4	-2.2	-2.0
<b>Ethical drugs business</b>	<b>Sales of new ethical drugs</b>		84.5	78.9	-5.6	-6.7
		<b>Japan</b>	83.8	75.5	-8.3	-9.9
		<b>Overseas</b>	0.8	3.3	+2.5	+331.9
	<b>Generic drugs</b>		25.0	28.5	+3.5	+13.9
<b>Healthcare Business</b>			5.8	5.9	+0.1	+1.6
<b>Operating Income</b>			10.4	<b>12.1</b>	+1.7	+16.2
<b>Ordinary Income</b>			10.9	<b>12.6</b>	+1.7	+15.9
<b>Net Income</b>			7.3	<b>9.7</b>	+2.4	+32.8

【for reference: year on year】

- ① Cost of sales ratio : decrease a little less than 1 point,
- ② R&D expenses decreased ( forecast for R&D expense in FY2107 : ¥12.6bln)
- ③ SG&A(excluding R&D) decreased ( SG&A ratio(include R&D expense): decreased 0.5% )

※Transfer the stocks of Dr. Program Co., Ltd. (skincare business) to Taisho Pharmaceutical Co., Ltd. in anticipation of extraordinary profit from the stock transfer



# Forecast of Mainstay Product Sales

( Units: ¥ billion )

	FY2016	FY2017 (forecast)	Y/Y	
			Change	Change(%)
<b>Flutiform</b> (Combination drug for asthma treatment)	10.1	<b>12.0</b>	+1.9	+19.9
<b>Uritos</b> (Overactive bladder)	7.5	<b>7.6</b>	+0.1	+1.8
<b>Desalex</b> (Antiallergic Agent)	1.0	<b>3.5</b>	+2.5	+262.3
<b>Kipres</b> (LT receptor antagonist)	32.7	<b>21.0</b>	-11.7	-35.4
<b>For children</b>	14.9	<b>11.1</b>	-3.8	-25.0
<b>Pentasa</b> (Ulcerative colitis and Crohn's disease treatment)	15.5	<b>15.6</b>	+0.1	+1.2
<b>Mucodyne</b> (Mucoregulant)	9.9	<b>8.3</b>	-1.6	-15.5
<b>MONTELUKAST Tablets "KM"※</b>	8.2	<b>10.3</b>	+2.1	+25.6

# Shareholder Returns

## Basic Policy

- While maintaining the sound financial base, adopt the capital policy ensuring both growth investment and stable return to shareholders.

- In shareholders return, aim for stable dividends.

Dividend per share for fiscal 2017 (estimate): ¥58 (Year-end dividend ¥38)

## Dividends




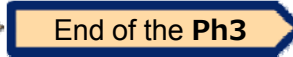

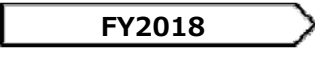


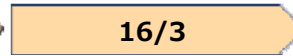
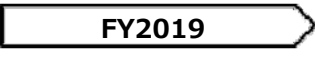



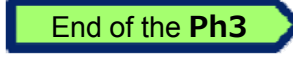

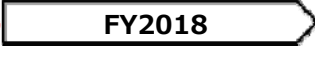

	FY2015	FY2016 ※	FY2017 (forecast)
Dividend per share (Yen)	¥58 (Year-end ¥38)	¥58 (Year-end ¥38)	¥58 (Year-end ¥38)
Consolidated payout ratio(%)	31.8%	59.3%	44.7%

※ The year-end dividend of 38 yen in the fiscal year ending March 2017 will be decided at the Board Meeting scheduled for May 23.

# **Status of development pipeline**

# Drug Development Pipeline: Progress in FY2016, schedule of FY2017

 progress in FY16  schedule of FY17

	Product & development code	Ph I	Ph II	Ph III	application	Approval/ Launch
Respiratory	<b>Ad-SGE-REIC</b>					
Infections	<b>KRP-AM1977X</b>					
	<b>KRP-AM1977Y</b>					
Otolaryngological	<b>KRP-209</b>					
	<b>Desalex</b>					
Urological	<b>KRP-114V</b>					
	<b>KRP-116D</b> ※1					

※1 Interstitial cystitis treatment: The development of dimethylsulfoxide was decided, an unapproved and off-label drug that is greatly needed in medical practices (fiscal year ending March 2014).

※2 2017/5

## 【 Licensing development】

開発コード	導出先	開発段階	特徴
<b>FPR2 agonist program</b>	BMS	Preclinical	FPR-2 agonists that mainly inhibit the migration of neutrophils and exhibit anti-inflammatory action. Therapy area : Non-disclosure
<b>KRP-203</b>	Novartis	Ph I	Sphingosine-1-Phosphate Receptor Agonist . Therapy area : GvHD

## ■generic name : Lascufloxacin (LSFX )

Status of development:  
KRP-AM1977X (Oral agent)

●Application(2017/4)

Status of development:  
KRP-AM1977Y (Injection)

●Clinical trials: Ph3(2016/3 Start)

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

### 【 Features】

**The drug has been shown to have a good clinical effect at 75 mg q.d. against community-acquired respiratory tract infections and ear/nose/throat infections.**

• The drug has strong antibacterial activity against bacteria inducing respiratory tract and ear/nose/throat infections as well as against strains resistant to  $\beta$ -lactam and macrolide antibiotics.

• The drug is highly transferable to the lung tissue with a plasma ratio greater than 10.

**The drug can be expected to be very safe.**

• The drug is very unlikely to induce problems that are typically concerns with antibacterial agents of the same type, such as abnormal glucose levels, photosensitivity, joint damage and digestive symptoms.

**aim to early approval of this drug**

# Overactive bladder treatment 「KRP-114V」

■generic name : Vibegron

## Status of development

### ●Preparing for Application

#### Clinical Phase III study

Study: A double-blind comparative study for verifying the efficacy and safety of the drug in OAB patients

Result: The drug was shown to be superior to a placebo in primary endpoints and all secondary endpoints.

**[Primary endpoints]** Average frequency of urination per day

**[Secondary endpoints]** Average frequency of urinary urgency per day, etc.

## 【 Features 】

- Expectation of high compliance in taking medicine with less side effects than the conventional drugs for overactive bladder
- Less drug interaction as  $\beta 3$  receptor agonist
- $\beta 3$  agonist including this agonist may constitute the first-line drug for treatment of overactive bladder.

•License agreement with Merck & Co., Inc.,(7/2014)

•Co-Development and Co-Marketing Agreement with Kissei Pharmaceutical Co., Ltd. affiliate . (3/2016)

■Kyorin acquired licenses from Merck & Co., Inc.,for Asia (4/2017)

**File an application and obtain approval soon**

**Progress of Medium-Term Business Plan  
“HOPE 100-Stage 2-” (Fiscal 2016~2019)**

## Business Strategy (S) Strategy

### 【Four Priority Strategies】

- ① Strengthening of the Ability to Discover New Drugs
- ② Increase in the Ratio of New Drugs Group
- ③ Promotion of Generic Drugs Business by Making the Most of Its Characteristics
- ④ Strengthening of Low Cost

### 【Development Strategies】

- Healthcare Business/ Overseas Expansion

## Organization Strategy (O) Organization

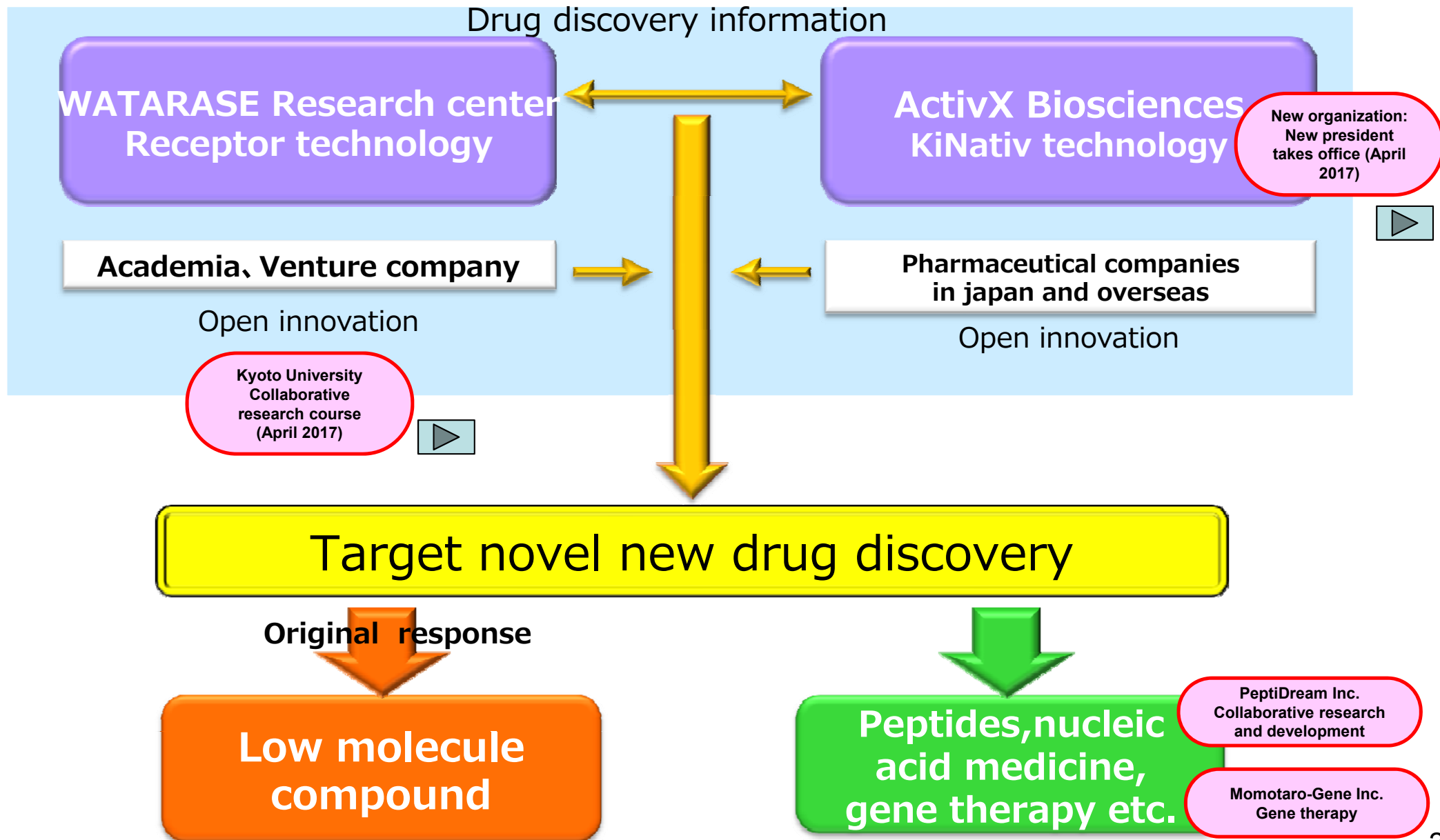
- Best worthwhileness of work
- Establishment and operation of the system for management of human resources

## Performance Targets (P) Performance

- Sustainable growth
- Aim to achieve the average annual growth rate of 3% or more for the consolidated net sales and the consolidated operating income margin of 15% or more.
- In shareholders return, aim for stable dividends.



**【Generation of innovative new drugs】**



## **[Profile]**

- **Born on January 23, 1959 (aged 58)**
- **1982: Graduated from the University of Cape Town**  
Obtained a medical license the same year
- **1986: Received a Ph.D. from the University of Oxford**
- **1991: Joined Merck**
- **2002: Assumed role of Scripps Professor**



## **[His relationship with ActivX and Kyorin Pharmaceutical Co., Ltd. so far]**

- **ActivX Scientific Advisor since 2002**
- **Sent Kyorin's researchers to Scripps' Rosen Laboratory since 2006**  
Subsequently, sent six researchers by 2012 and contributed to their development
- **Scientific Advisor for Kyorin Pharmaceutical Co., Ltd. since 2012**

## ■Objective

With the aim of creating innovative Japanese therapeutic drugs, find new targets for drug discovery by combining Kyoto University graduate school's abilities in pathological and basic studies and Kyorin Pharmaceutical's abilities to develop drugs, identifying numerous factors that are deeply involved in the pathological causes of respiratory diseases and verifying potential targets for drug discovery.

- Research the pathological causes of lung fibrosis and other organ fibrosis processes based on Kyoto University and Kyorin technologies.
- Apply the technical infrastructure using iPS cells and improve the quality of evaluation for drug discovery.

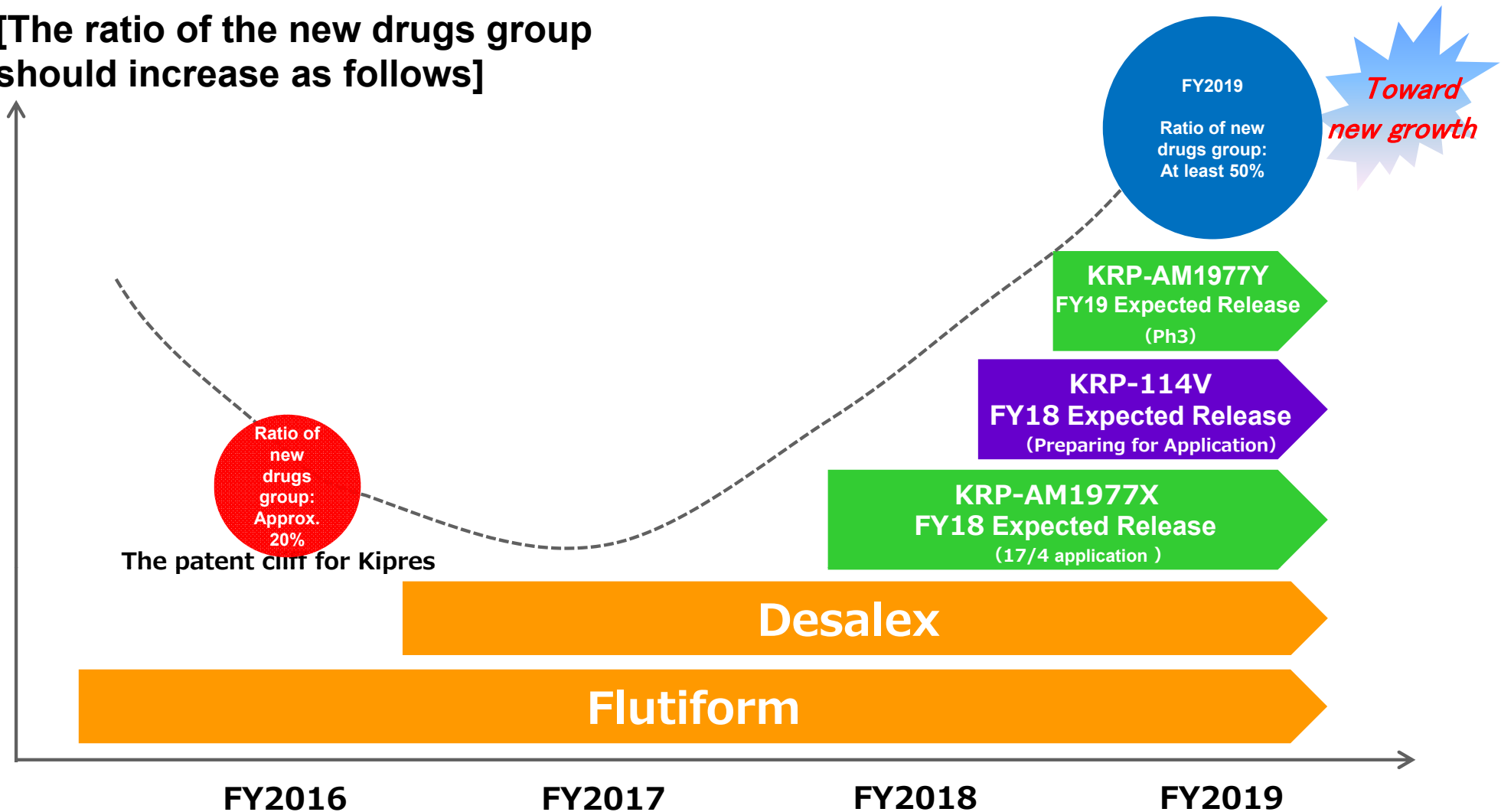
## ■Information

- Location : Graduate School of Medicine, Kyoto University
- Course title : Respiratory Disease Drug Discovery Course
- Instructors : Shinpei Gotoh, M.D., Ph.D.  
(formerly Department of Respiratory Medicine, Graduate School of Medicine, Kyoto University)  
: Masayasu Toyomoto, Ph.D.  
(formerly Department of Anatomy and Developmental Biology, Graduate School of Medicine, Kyoto University)
- Period : April 1, 2017 – March 31, 2020
- Amount of funding : Approx. 50 million yen/year

# Substantial increase in the ratio of new drugs group by maximizing spread of new drugs group

- Maximize the spread of Flutiform and Desalex.
- Successfully launch new products so that they will become soon entrenched in the market (KRP-AM1977X·Y and KRP-114V).

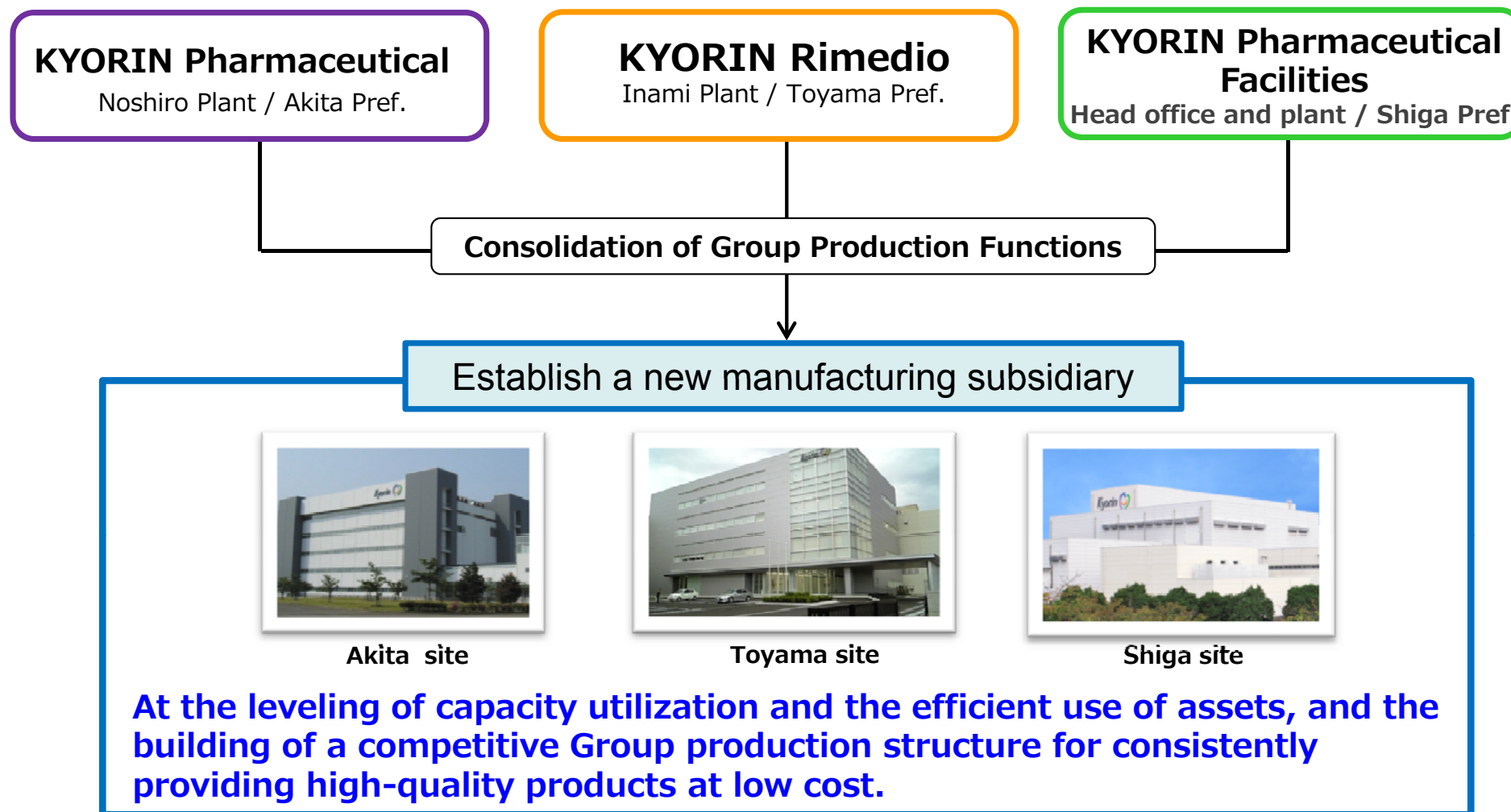
[The ratio of the new drugs group should increase as follows]



# Change of the cost structure by ensuring optimization within the Group

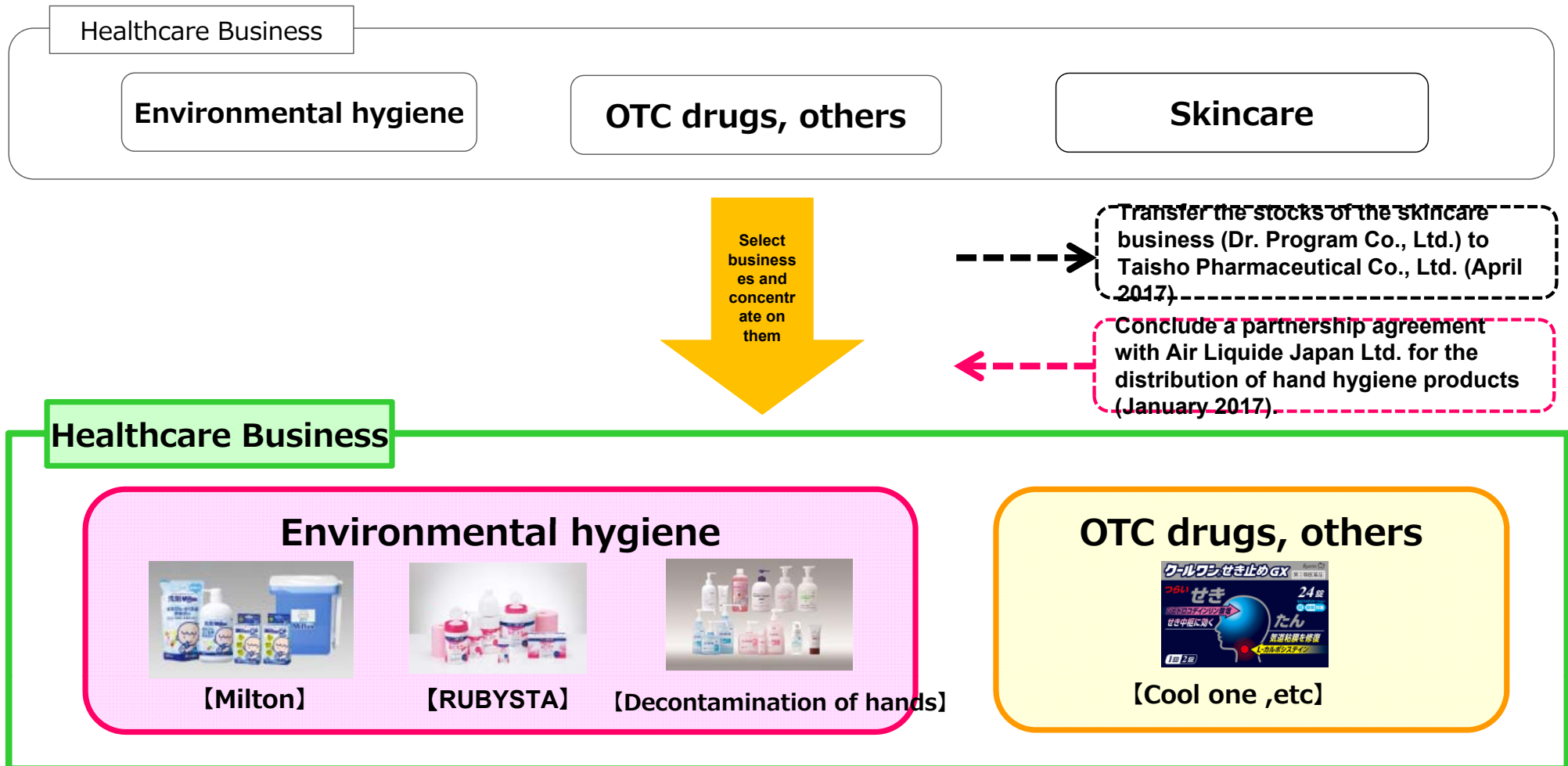
It has resolved its held on the direction to consolidate production functions of the KYORIN Group into such new subsidiary. (2017/5/11)

## 【 Image of Consolidation of Group Production Functions】



# Developing a core and paving the way for a candidate for the next core

## 【 About Healthcare Business】



**Expand the environmental hygiene business and grow it into a core business.**

# Important points in facilitating the FY2017 business strategy

**Properly react to discontinuous and sudden changes in our business and achieve sustainable growth over the medium and long terms.**

**Increase awareness about profitability**

**Build the basis for continued growth**