

Financial Results for Fiscal 2017

May 11 , 2018
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 2017



(unit : ¥billion)

	FY2016	FY2017	Change	Change (%)	Change (revised forecast)
Net Sales	115.4	110.6	-4.8	-4.1	-0.7
Operating Income	10.4	8.8	-1.6	-15.3	-1.7
Ordinary Income	10.9	9.3	-1.6	-14.1	-1.6
Net Income	7.3	6.6	-0.7	-10.0	-1.2

Breakdown of Gain and Loss

(unit : ¥billion)

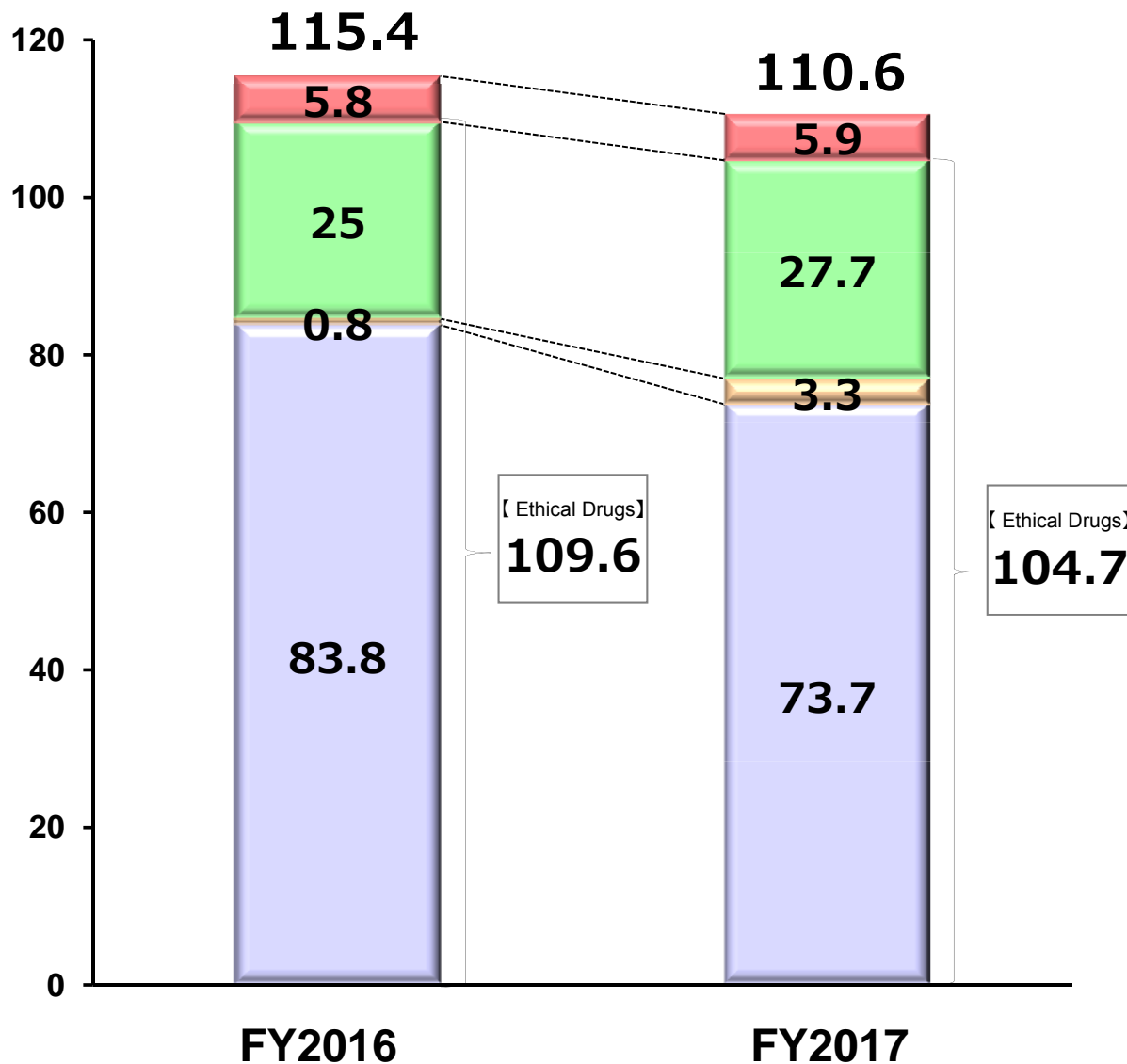
	FY2016	FY2017	Change	Change (%)	Change (revised forecast)	
Net Sales	115.4	110.6	-4.8	-4.1	-0.7	
	109.6	104.7	-4.9	-4.4	-0.6	
Ethical drugs business	Sales of new ethical drugs	84.5	77.0	-7.5	-8.9	-0.2
	Japan	83.8	73.7	-10.1	-12.0	-0.5
	Overseas	0.8	3.3	+2.5	+337.0	+0.3
	Generic drugs	25.0	27.7	+2.7	+10.5	-0.3
Healthcare Business	5.8	5.9	+0.1	+2.2	0	
Cost of Sales	50.8	49.1	-1.7	-3.5	-	
SG&A	54.1 (13.6)	52.8 (14.2)	-1.3 (+0.6)	-2.5 (+5.0)	- (+1.2)	
Operating Income	10.4	8.8	-1.6	-15.3	-1.7	
Ordinary Income	10.9	9.3	-1.6	-14.1	-1.6	
Net Income	7.3	6.6	-0.7	-10.0	-1.2	

- **Extraordinary income** : gain of approximately 600 million yen as a result of transfer of shares of Dr. Program Co., Ltd. Recorded.
- **Extraordinary loss** : Expenses of around 400 million yen related to the settlement of a lawsuit for violation of US antitrust laws in connection with an out-licensed product (Gatifloxacin eyedrops).
Loss due to debt guarantee regarding a trust-type employee stock ownership incentive plan: About 400 million yen

Highlights of Business Performance ① (Sales) *Kyorin*

健康はキョーリンの願いです。

(Units: ¥ billion)



【 Net Sales ¥-4.8bln】

Healthcare Business +0.1bln

- The distribution of hand hygiene products sales start
- Growth of RUBYSTA and Milton
- Transfer the stocks of the skincare business

【 Ethical Drugs Sales ¥-4.9bln】

Generic drugs +2.7bln

- Increase of MONTELKAST AG sales
- Sales to other companies decreased

Ethical drug sales overseas +2.5bln

- received lump sum payment of out-licensed product

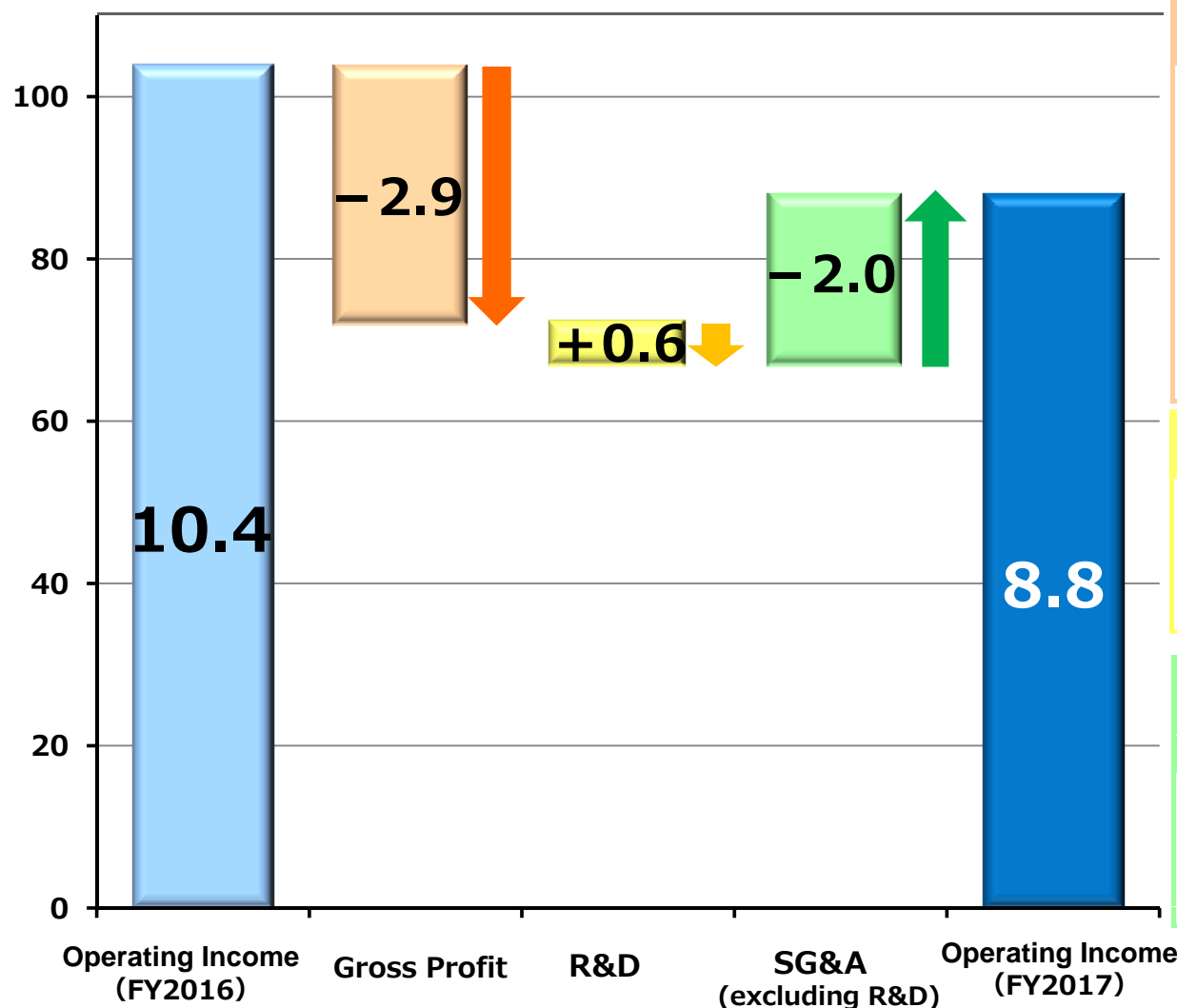
Ethical drug sales in Japan - 10.1bln

- Despite steady growth in Flutiform and Desalex sales
- Decreased by the expiration of the patent for KIPRES.
- Decreased in prescriptions of long-listed drugs.

Highlights of Business Performance ② (Income)

(Units: ¥ billion)

【Operating Income ¥ – 1.6bln】



Gross Profit decreased

Net Sales :
decreased ¥4.8bln year on year

Cost of sales ratio :
Increased 0.2% year on year

- Decrease of sales of new ethical drugs
- Increase in loss on retirement of inventories, etc.
- Increased costs due to the impact of currency fluctuations

R&D expenses increased

- Book a lump-sum payment for the contract for the introduction of KRP-N118 (SK-1404)
- ¥13.6billion (FY2016)
⇒¥14.2billion(FY2017)

SG&A(excluding R&D) decreased

- Decrease of Labor costs, general expenses
- ¥40.5billion(FY2016)
⇒¥38.5billion(FY2017)

Highlights of Business Performance ③

(Change : original forecast)



(Units: ¥ billion)			FY2017 (forecast)	FY2017 (actual)	Change	Change (%)	Change (revised forecast)
Net Sales			111.3	110.6	-4.8	-4.1	-0.7
			105.3	104.7	-4.9	-4.4	-0.6
Ethical drugs business	Sales of new ethical drugs	Japan	77.2	77.0	-7.5	-8.9	-0.2
			74.2	73.7	-10.1	-12.0	-0.5
		Overs eas	3.0	3.3	+2.5	+337.0	+0.3
	Generic drugs		28.0	27.7	+2.7	+10.5	-0.3
Healthcare Business			5.9	5.9	+0.1	+2.2	0
Cost of Sales			-	49.1	-1.7	-3.5	-
SG&A			- (13.0)	52.8 (14.2)	-1.3 (+0.6)	-2.5 (+5.0)	- (+1.2)
Operating Income			10.5	8.8	-1.6	-15.3	-1.7
Ordinary Income			10.9	9.3	-1.6	-14.1	-1.6
Net Income			7.8	6.6	-0.7	-10.0	-1.2

【Explanation of Variances (Change : revised forecast)】

Net sales: Regarding the new drug launched in Japan, sales of Kipres and products for other companies did not achieve the target, and sales of generic medicine for other companies did not achieve the target.

R&D cost: Booked a lump-sum payment for the contract of the license-in product: 13.0 billion yen (forecast)→14.2 billion yen +1.2 billion yen

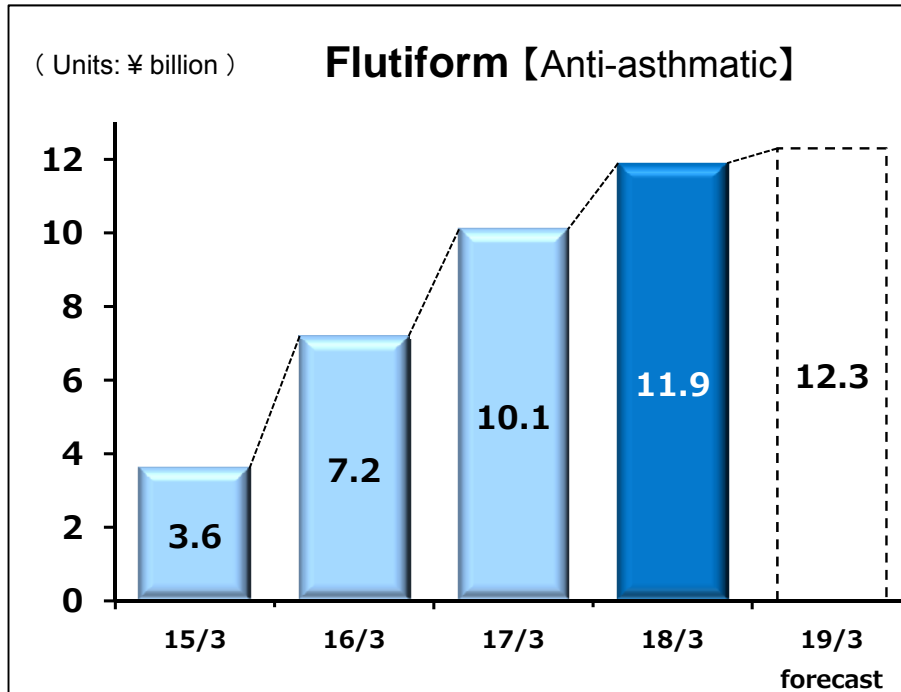
Mainstay Product Sales

(Units: ¥ billion)

	FY2016	FY2017	Change	Change(%)	Change (revised forecast)
Flutiform (Combination drug for asthma treatment)	10.1	11.9	+1.8	+18.1	-0.1
Uritos (Overactive bladder)	7.5	7.2	-0.3	-3.7	-0.1
Desalex (Antiallergic Agent)	1.0	4.9	+3.9	+404.8	+1.4
Kipres For adult (LT receptor antagonist)	17.7	8.3	-9.4	-53.5	-0.8
----- For children	14.9	10.5	-4.4	-29.5	-0.2
Pentasa (Ulcerative colitis and Crohn's disease treatment)	15.5	15.3	-0.2	-1.4	-0.3
Mucodyne (Mucoregulant)	9.9	8.7	-1.2	-12.1	+0.3
MONTELUKAST Tablets"KM"	8.2	11.7	+3.5	+42.4	+1.0

Trends of mainstay products

■ Respiratory/Otolaryngology



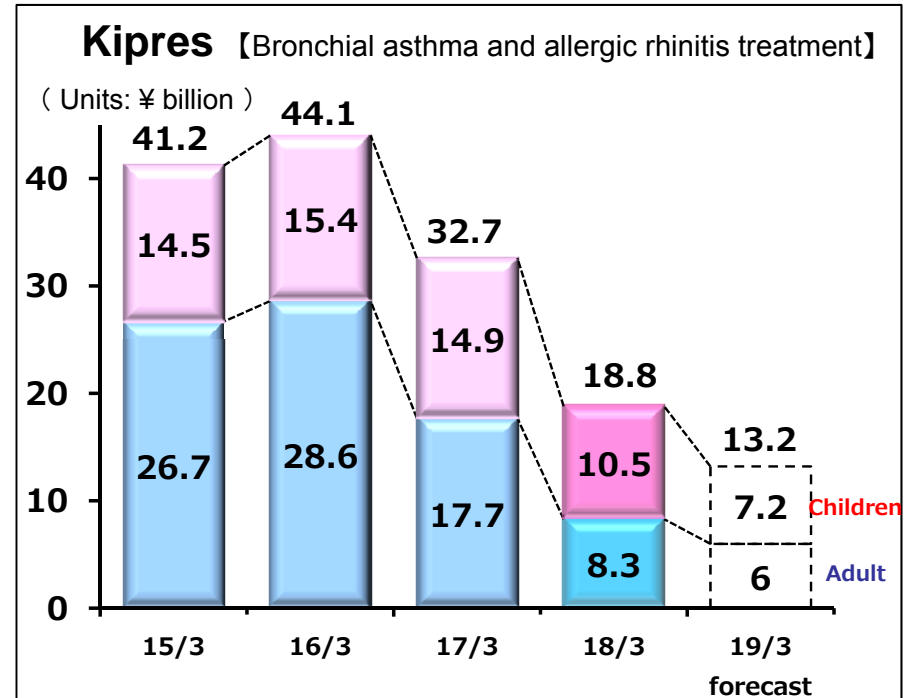
■status of FY2017

- ICS/LABA market : expand 1.3%
¥113.6bln (FY2016) ⇒ ¥115.1 (FY2017) ※1
- share of Flutiform sales
9.7% (FY2016) ⇒ 11.4% (FY2017) ※2
[price revision rate ▲5.8%]

■effort for FY2018

- Secure the positioning of a first-line drug for the treatment of asthma
- ・Attract attention to the high clinical impact from a patient with symptoms
 - ・The agent nicely penetrates and reaches the peripheral airways.

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■status of FY2017

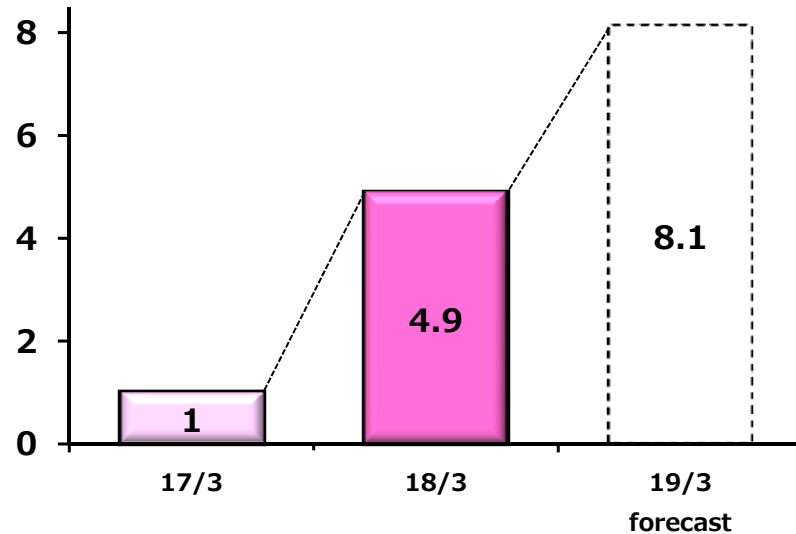
- LT antagonists market : shrink 19.2%
¥ 113.2 (FY2016) ⇒ ¥91.4 (FY2017) ※1
- share of Kipres sales
33.9% (FY2016) ⇒ 24.6% (FY2017) ※2
[price revision rate ▲10.2%]

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■ Respiratory / Otolaryngology

(Units: ¥ billion)

Desalex(Antiallergic Agent)



■status of FY2017

●Antihistamine market : expand 2.7%
¥173.5bln (FY2016) ⇒ ¥178.2 (FY2017) ※1

●share of Desalex sales

0.5% (FY2016) ⇒ 2.9% (FY2017) ※2
【price revision rate ▲5.6%】

※ The prescription restriction lifted in December 2017

■effort for FY2018

- non-drowsy and effects and usability
- Realization of prescription acquisition rate No.1 in otolaryngology

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Nasonex (Spray type allergic rhinitis remedy)

Concluded co-promotion contract with MSD (Sep. 2016)

■ Acquire domestic exclusive distribution rights (May.2018)

[Sales start] August 2018 (planned)

[Sales forecast] Fiscal year ending March 2019:
10.1 billion yen

● Market scale : 43 billion yen※

Main products : NASONEX ,Allermist,Erizas,Flunase, etc

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【 Product features】

Efficacy : Steroid nasal spray

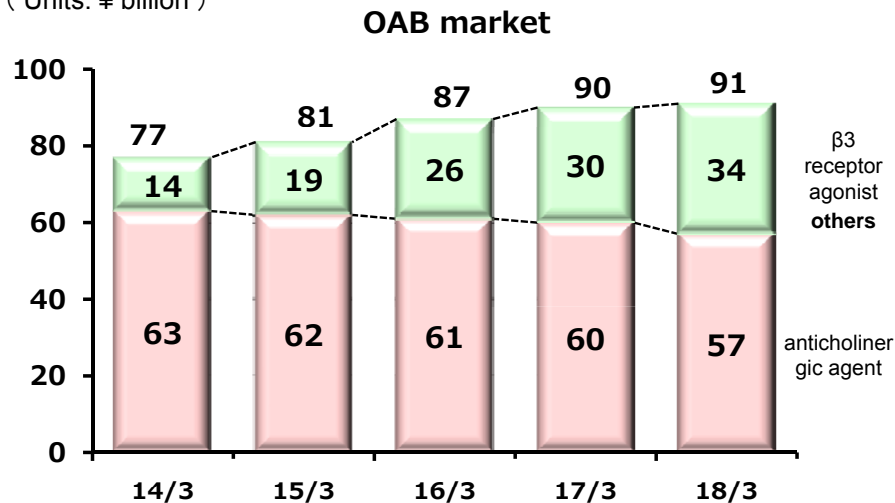
Indication : Allergic rhinitis

Feature : Single daily dose of steroid nasal spray is exceptionally effective against symptoms of allergic rhinitis (sneezing, runny nose, nasal congestion, nasal pruritus)



Urology

(Units: ¥ billion)



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■ OAB market expand

¥77.0bln (FY2013) ⇒ ¥91.0 (FY2017) ※1

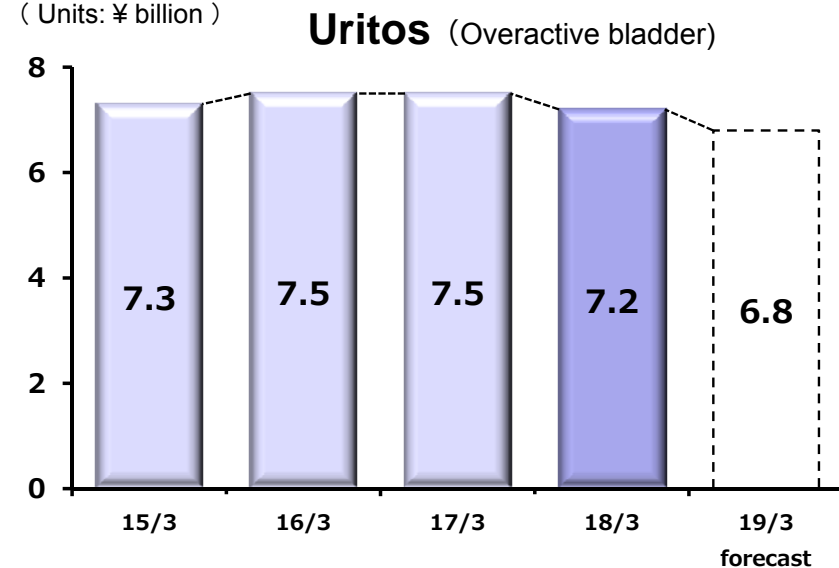
● Launch of β3 receptor agonist

- Launch a new drug (KRP-114V) to contribute to the treatment of patients with an overactive bladder (OAB)
- Establish the positioning of Uritos

With both drugs, we aim to expand the market share in the OAB market.

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(Units: ¥ billion)



■ status of FY2017

● OAB market : market : expand 0.8%

¥90.0bln (FY2016) ⇒ ¥91.0 (FY2017) ※1

● share of Uritos sales

9.2% (FY2016) ⇒ 8.8% (FY2017) 注2

【 price revision rate ▲5.9%】

■ effort for FY2018

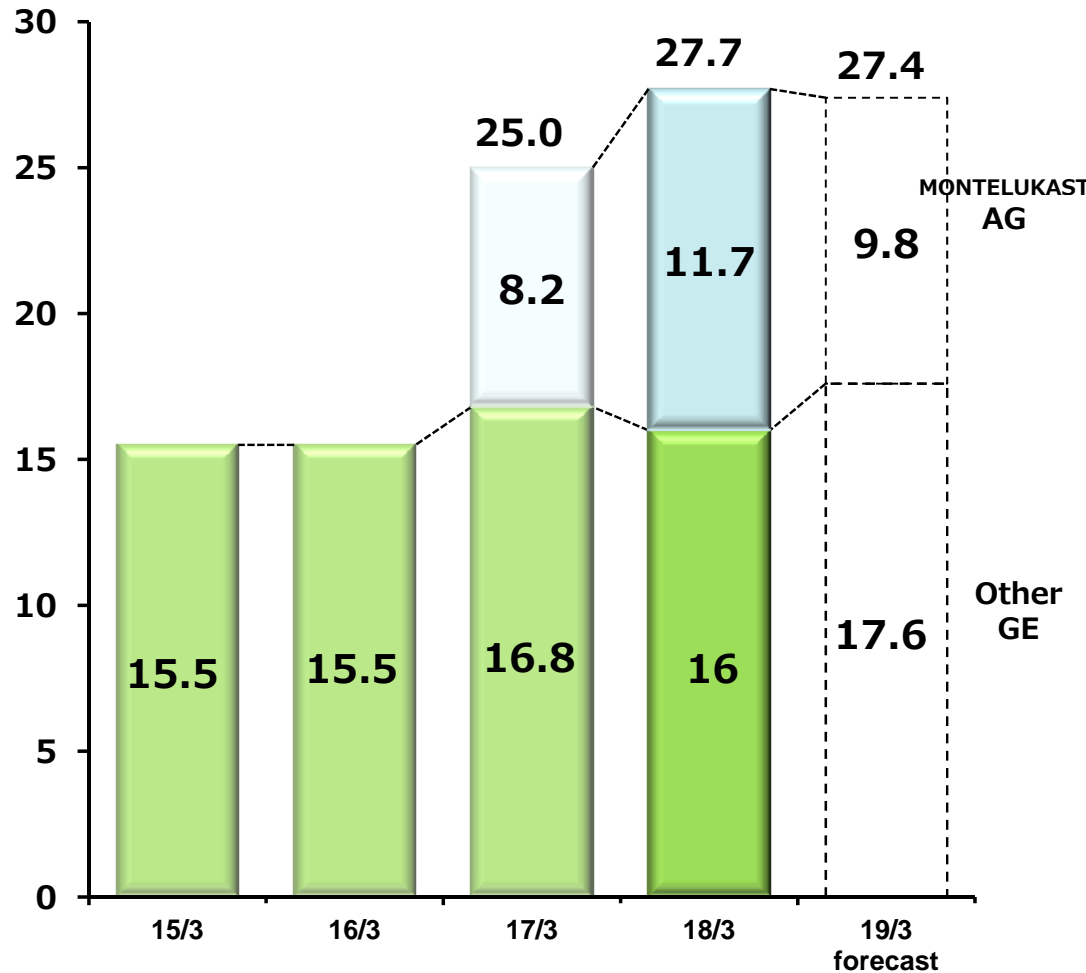
● Aim to be a firstline drug for OAB patients with nocturia

- Promotion of prescription based on extensive evidence

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■ Status of Generic Drugs

(Units: ¥ billion)



■ status of FY2017

- Turnover increase , MONTELUKAST AG: + ¥ 3.5bln
【 price revision rate ▲18.0%】
- Turnover decrease rate, excluding AG
 - ・ Increase of Health insurance pharmacy market's sales
 - ・ Decrease of contract manufacturing's sales

■ effort for FY2018

- **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**

Consolidated Financial Results and Forecast

Consolidated Financial Results Forecast for the Year Ending March 31, 2019



(Units: ¥ billion)

	FY2017	FY2018 (forecast)	Y/Y		
			Change	Change(%)	
Net sales	110.6	114.4	+3.8	+3.4	
Ethical drugs business	104.7	108.4	+3.7	+3.5	
	Sales of new ethical drugs	77.0	80.9	+3.9	+5.0
	Japan	73.7	79.9	+6.2	+8.4
	Overse as	3.3	1.0	-2.3	-70.1
Generic drugs	27.7	27.4	-0.3	-0.9	
Healthcare Business	5.9	6.0	+0.1	+1.1	
Operating Income	8.8	8.6	-0.2	-2.5	
Ordinary Income	9.3	9.2	-0.1	-1.6	
Net Income	6.6	6.6	0	+0.4	

【for reference: year on year】

- ① Increase sales of our main products Flutiform and Desalex, and increase sales of Nasonex.
- ② Reduction of gross operating income: The cost rate is up by about 4 point.
- ③ Reduction of selling, general and administrative expenses (SGA): R&D cost is reduced (forecast a reduction of 2.6 billion yen from the previous year, to 11.6 billion yen). The rate of SGA (excluding R&D cost) has declined by about 1% from the previous year.
- ④ Method of depreciation: Expect a change from the declining-balance method to the straight-line method.

Forecast of Mainstay Product Sales

(Units: ¥ billion)

	FY2017	FY2018 (forecast)	Y/Y	
			Change	Change(%)
Flutiform (Combination drug for asthma treatment)	11.9	12.3	+0.4	+4.1
Uritos (Kyorin) (Overactive bladder)	7.2	6.8	-0.4	-4.7
Desalex (Antiallergic Agent)	4.9	8.1	+3.2	+65.3
Kipres for adult (LT receptor antagonist)	8.3	6.0	-2.3	-26.8
Kipres for children (LT receptor antagonist)	10.5	7.2	-3.3	-30.9
Pentasa (Ulcerative colitis and Crohn's disease treatment)	15.3	14.5	-0.8	-5.0
Mucodyne (Mucoregulant)	8.7	7.2	-1.5	-16.5
Nasonex (Spray type allergic rhinitis remedy)	—	10.1	+10.1	—
MONTELUKAST Tablets "KM"	11.7	9.8	-1.9	-16.4

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 2018 (estimate): ¥58 (Year-end dividend ¥38)

Dividends

	FY2016	FY2017 ※	FY2018 (forecast)
Dividend per share (Yen)	¥58 (Year-end ¥38)	¥58 (Year-end ¥38)	¥58 (Year-end ¥38)
Consolidated payout ratio(%)	59.3%	65.9%	65.7%

※ The year-end dividend of 38 yen in the fiscal year ending March 2018 will be decided at the Board Meeting scheduled for May 22.

Status of development pipeline

Drug Development Pipeline: Progress in FY2017, schedule of FY2018



progress in FY17 schedule of FY18

	development code	Ph I	Ph II	Ph III	application	Approval/ Launch
Respiratory	Ad-SGE-REIC	End of the Ph I / Ph II				
	KRP-108P		Ph II start			
Infections	KRP-AM1977X				2017/6	
	KRP-AM1977Y				2017/4	FY19 Expected Release
Urological	KRP-114V				preparation	
	KRP-116D				2017/9	FY18 Expected Release
	KRP-N118 (SK-1404)		Ph II start			

【 Licensing development 】

※ For KRP-AM 1977 X, additional nonclinical studies are required and will be carried out.

Compound/Code	導出先	Stage	Features
FPR2 agonist program	BMS	Ph I	FPR-2 agonists that mainly inhibit the migration of neutrophils and exhibit anti-inflammatory action. Therapy area : Non-disclosure

※KRP-203: Because Novartis (licensee) decided to discontinue development of KRP-203 for strategic reasons,kyorin receive the return of development rights.

■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.

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

Publication of the results of the study

- ・Conference presentation: March 2018 European Association of Urology (EAU)
- ・Publication of a paper: Specialty urology journal: European Urology (May issue)

File an application and obtain approval soon

Therapeutic Agent for Nocturia: KRP-N118



Concluded a licensing agreement with Sanwa Kagaku Kenkyusho Co., Ltd.
(March 2018)

[Development status] Phase II clinical study

[Mechanism of action]

A vasopressin V2 receptor agonist that promotes the reabsorption of water by the collecting duct of the kidney to reduce the amount of urine (antidiuretic action).

[Characteristics]

The drug is well absorbed and evidences antidiuretic action promptly after administration. The drug is eliminated rapidly from the body. It is expected to be a **therapeutic agent for nocturia due to nocturnal polyuria** that offers good efficacy and safety.

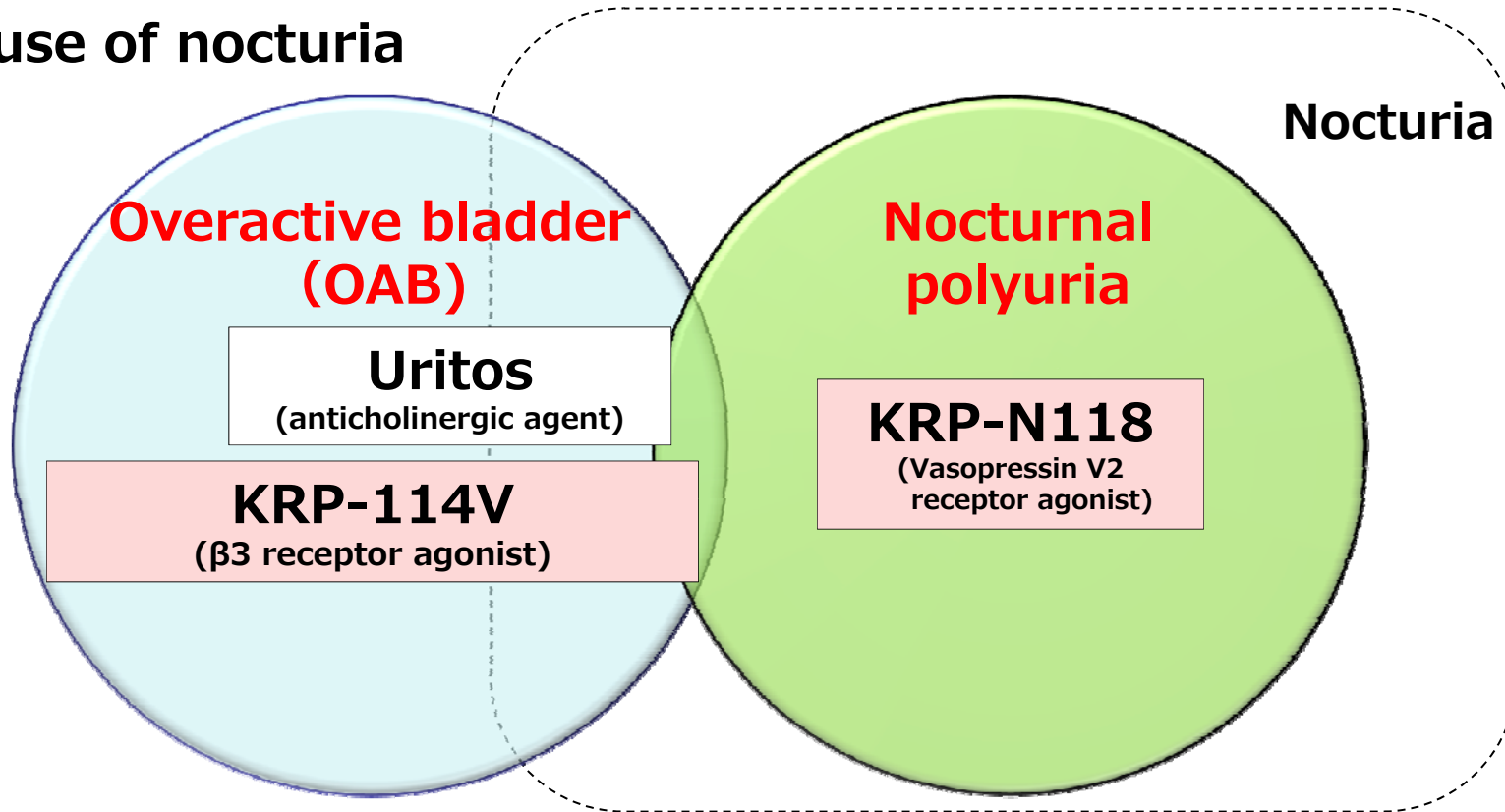
What is Nocturia?

Nocturia is a disease with symptoms that cause a patient to get up to urinate during the night. It is the most common of the symptoms related to urination, and about 45 million males and females in their 40s and older have symptoms of nocturia, causing them to get up at least once to urinate during the night. The frequency increases with advancing age. Nocturia is a disease that causes a high level of difficulty in daily life.

(from the website of The Japanese Urological Association)

Expansion of product lineup in the area of urology

Cause of nocturia



Interstitial cystitis
KRP-116D is under development

Aim to improve presence in the area of urology

(Reference)	
■ Number of OAB patients 104 million (aged 40 years and older)* ¹	■ Number of patients with nocturia 45 million (at least one instance of urination during the night) 85 million (3 or more instances of urination during the night)* ²
Source: *1: Clinical guidelines for overactive bladder (ver. 2) *2: Honma et al., Epidemiological study of urination (2003)	

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

Outline of“HOPE 100-Stage 2-”

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

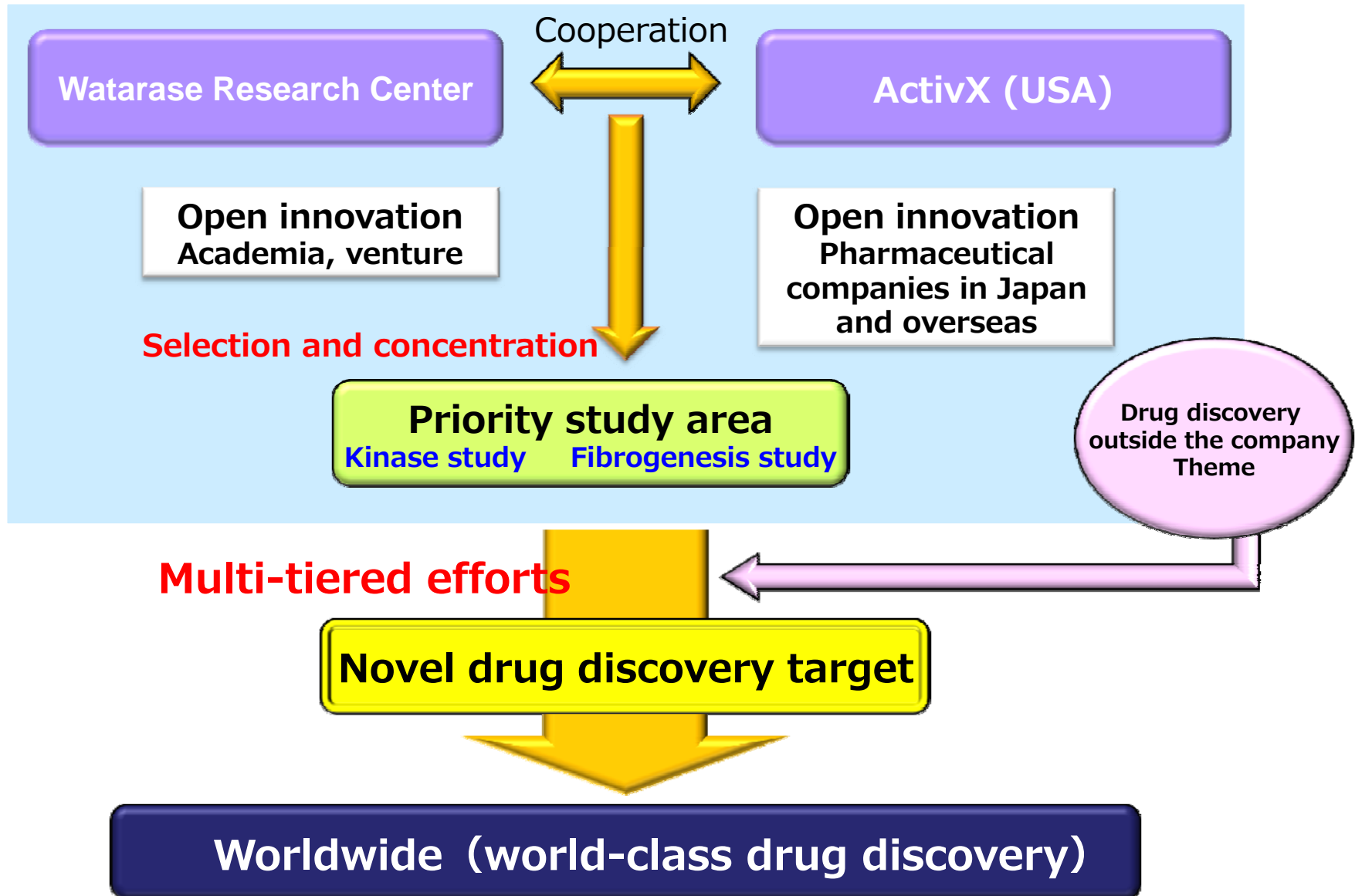
- Best worthwhileness of work
- Establishment and operation of the system for management of human resources

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.

Priority strategy: Enhance drug discovery capabilities

Efforts on first-in-class drug discovery

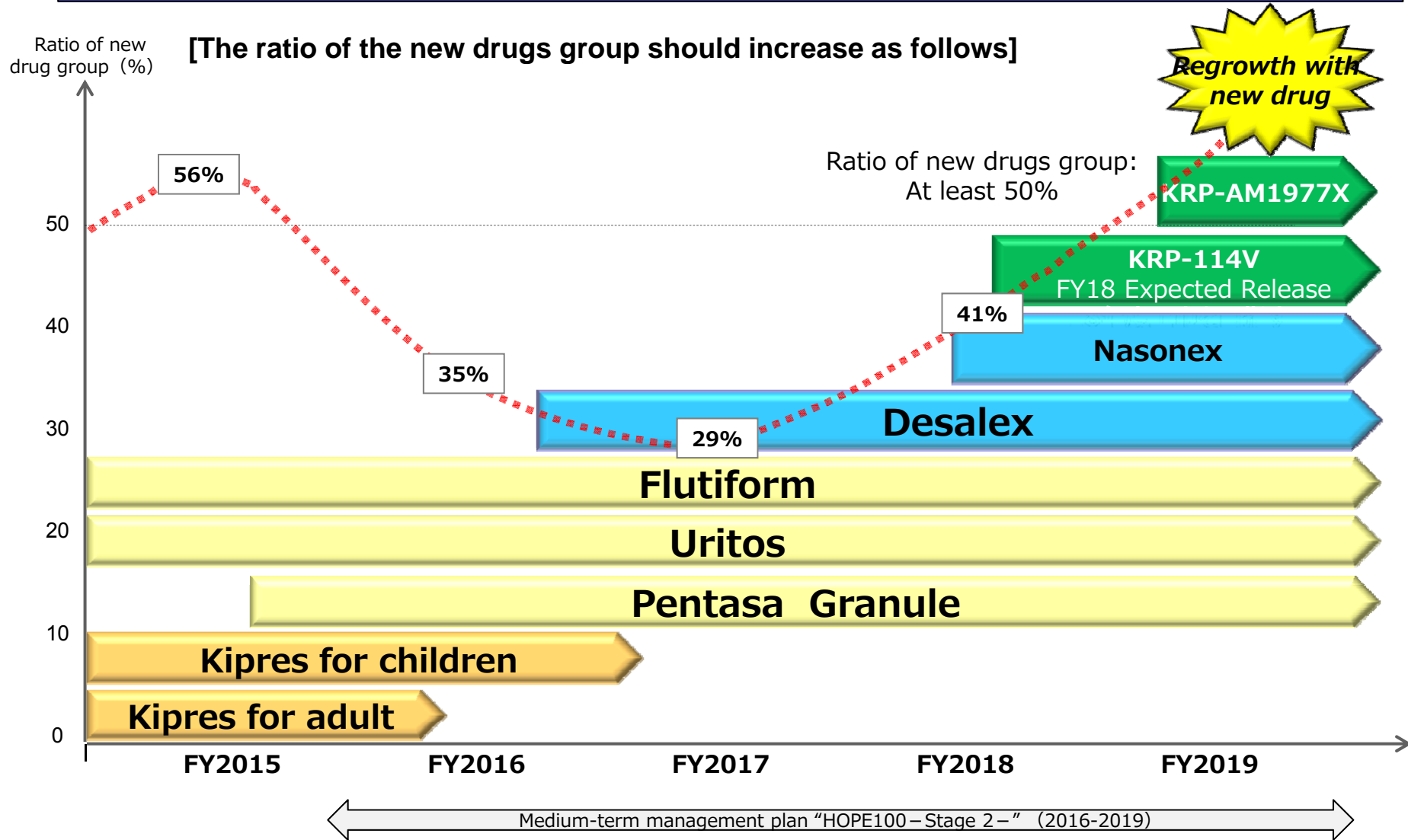


Priority strategy: Increase ratio of new drug group

Accelerate regrowth with new drug group and new products



- Maximize the dissemination of Flutiform, Desalex, PENTASA Granules, Uritos and Nasonex.
- Launch and disseminate KRP-114V and KRP-1977X.



Promotion of low-cost operation

■ Consolidation of the Group's production functions

Noshiro plant (Akita)



Inami plant (Toyama)



Shiga plant (Shiga)



**New production subsidiary: KYORIN Pharmaceutical Facilities Co., Ltd.
Commences full-scale operation on April 1, 2018**

**Equalization of the utilization rate of each plant, the efficient use of assets,
and the building of the Group's competitive production structure**

**■ Improvement of productivity through the betterment of the direct-indirect ratio
Promotion of appropriate number and deployment of employees (review of
existing operations and structures)**

Deployment of diagnostic business using GeneSoC ultrafast gene quantitative system

■ Characteristics of GeneSoC ultrafast gene quantitative system

- Rapid detection of genes based on the technology of ultrafast quantitative PCR* (5-6 minutes)
- High-sensitivity detection is possible with a trace amount of the sample immediately after infection
- A compact, desktop PCR device eyeing POCT*



■ GeneSoC Ultrafast gene quantitative system

Identification of pathogenic bacteria of infection by POCT and improvement of treatment with the choice of an appropriate antibacterial agent

PCR: Polymerase chain reaction, technology for gene amplification.

POCT: Point of care testing by a health care worker. It refers to tests conducted by a health care worker at an examinee's side. By taking advantage of the reduced test time and the advantage, that examinees feel is closer and more comfortable, POCT contributes to rapid and appropriate diagnosis and care, prevention of disease, promotion of health, and also to the improvement of medical care and patient QOL.

Efforts going forward

- **Release of a reagent for research using GeneSoC ultrafast gene quantitative system**
 - February 2019: Exhibition at the 30th annual meeting of the Japanese Society for Clinical Microbiology and launch within the fiscal year
- **Development of an extracorporeal (in-vitro) diagnostic agent**
 - Aim to launch in 2020

Target market

- Respiratory infections: Cold, pneumonia, influenza ● enteral infection ● sexually transmitted disease, etc.

Aim to be the next core business

Important points in facilitating the FY2018 business strategy

Make a change in advance and create a new scenario for growth

**Enhancement of
the basis for growth**

**Improvement of
earning power**

- Drug discovery of an original new drug
- Drug discovery of a new drug and creation of a market with a new drug
- Acceleration of growth of peripheral businesses and improvement of profitability
- Promotion of low-cost operation