

Financial Results for Fiscal 2018

May 14 , 2019
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 2018



(unit : ¥billion)

	FY2017	FY2018	Change	Change (%)	Change (revised forecast)	Change (original forecast)
Net Sales	110.6	113.6	+3.0	+2.7	+3.0	-0.8
Operating Income	8.8	9.0	+0.2	+1.7	+0.8	+0.4
Ordinary Income	9.3	9.4	+0.1	+1.0	+0.8	+0.2
Net Income	6.6	6.9	+0.3	+4.5	+0.8	+0.3

Breakdown of Gain and Loss

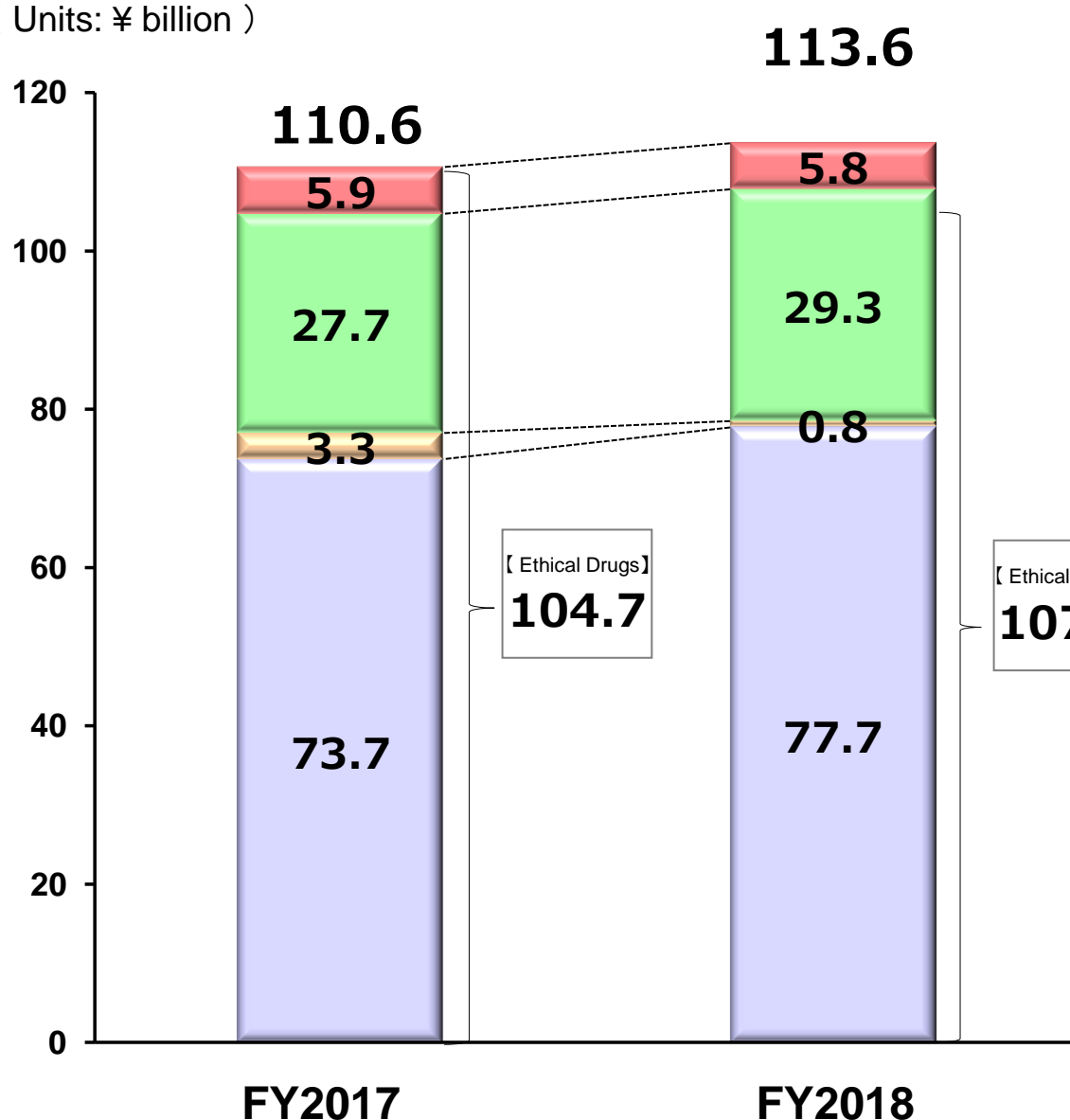
(unit : ¥billion)

			FY2017	FY2018	Change	Change (%)	Change (revised forecast)	Change (original forecast)
Net Sales			110.6	113.6	+3.0	+2.7	+3.0	-0.8
Ethical drugs business			104.7	107.9	+3.2	+3.0	+3.3	-0.5
	Sales of new ethical drugs		77.0	78.5	+1.5	+1.9	+1.4	-2.4
		Japan	73.7	77.7	+4.0	+5.4	+1.6	-2.2
		Overseas	3.3	0.8	-2.5	-75.1	-0.2	-0.2
	Generic drugs		27.7	29.3	+1.6	+6.0	+1.9	+1.9
Healthcare Business			5.9	5.8	-0.1	-3.0	-0.2	-0.2
Cost of Sales			49.1	56.2	+7.1	+14.6	-	-
SG&A			52.8 (14.2)	48.4 (10.8)	-4.4	-8.2	-	-
Operating Income			8.8	9.0	+0.2	+1.7	+0.8	+0.4
Ordinary Income			9.3	9.4	+0.1	+1.0	+0.8	+0.2
Net Income			6.6	6.9	+0.3	+4.5	+0.8	+0.3

Highlights of Business Performance ① (Sales) *Kyorin*

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(Units: ¥ billion)



【 Net Sales ¥+3.0bn】

【 Ethical Drugs Sales ¥+3.2bn】

Ethical drug sales in Japan +4.0bn

- Despite steady growth in Flutiform sales
- The release of Beova and transfer of the sale of Nasonex contributed.
- ※ Impact of drug price revisions (approximately 7%)

Ethical drug sales overseas -2.5bn

- Decrease in lump-sum revenue due to out-licensed product in the previous year

Generic drugs +1.6bn

- Increase in sales of generic drugs released in fiscal 2018

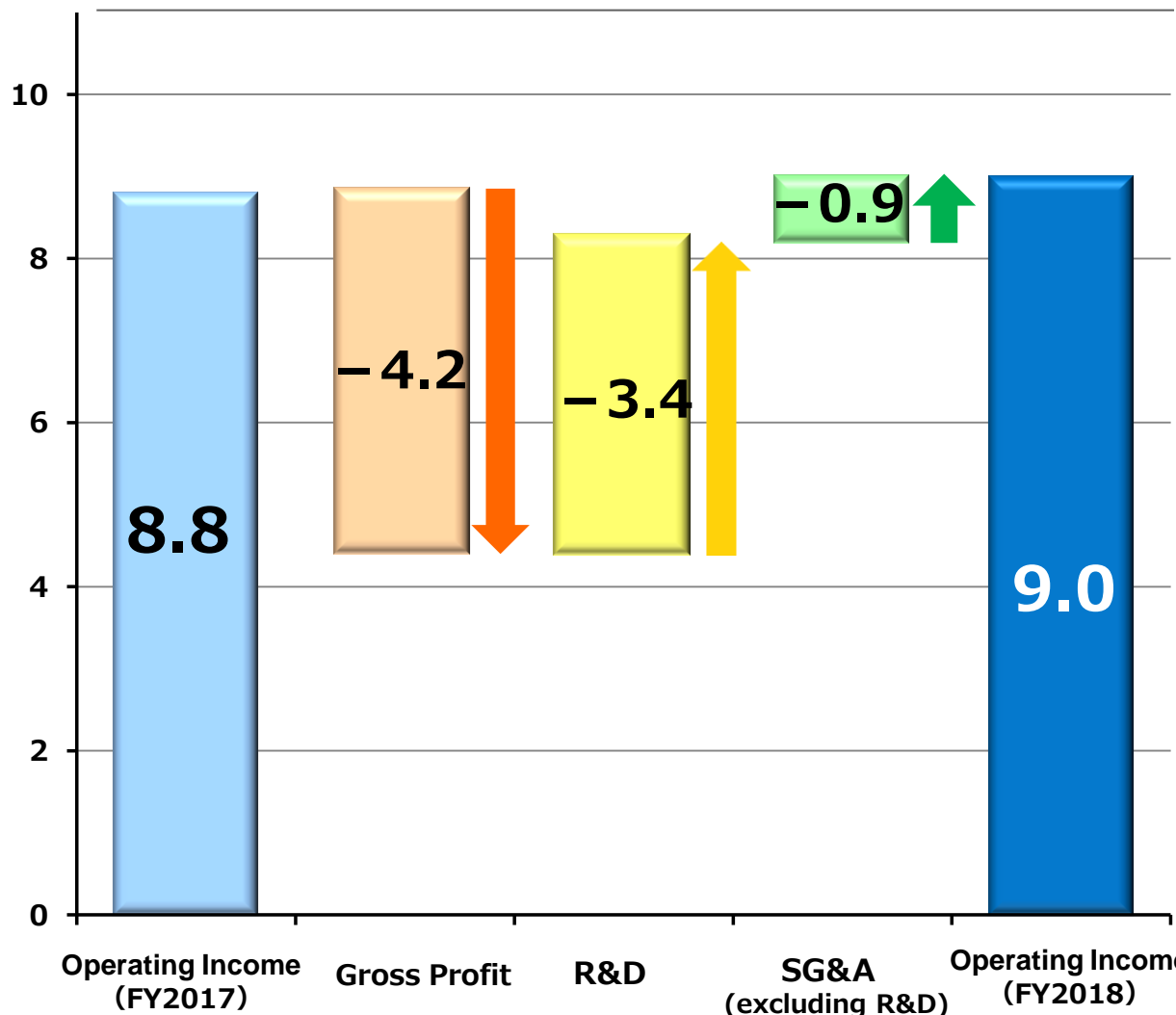
Healthcare Business -0.1bn

- Growth of RUBYSTA
- Sales of Milton and other products declined.

Highlights of Business Performance ② (Income)

(Units: ¥ billion)

【Operating Income ¥ + 0.2bln】



Gross Profit decreased

Net Sales :
 Increased ¥3.0bln year on year

Cost of sales ratio :
 decreased 5.1% year on year

- Impact of drug price revisions (approximately 7%)
- Increase in sales of generic drugs
- Decrease in lump-sum revenue due to out-licensed product in the previous year

R&D expenses decreased

¥14.2bln (FY2017) ⇒ ¥10.8bln (FY2018)

- Decrease in lump-sum contractual payments paid in conjunction with the introduction of KRP-N118
- Decrease due to the progress in the development project (fiscal year ended March 31, 2018)

SG&A(excluding R&D) decreased

• Decrease of Labor costs, Selling costs
 ¥38.5bln (FY2017) ⇒ ¥37.6bln (FY2018)

Highlights of Business Performance ③

(Change : forecast)

(Units: ¥ billion)	FY2017	FY2018	Change	Change (%)	Change (revised forecast)	Change (original forecast)	
Net Sales	110.6	113.6	+3.0	+2.7	+3.0	-0.8	
	104.7	107.9	+3.2	+3.0	+3.3	-0.5	
Ethical drugs business	Sales of new ethical drugs	77.0	78.5	+1.5	+1.9	+1.4	-2.4
	Japan	73.7	77.7	+4.0	+5.4	+1.6	-2.2
	Overs eas	3.3	0.8	-2.5	-75.1	-0.2	-0.2
	Generic drugs	27.7	29.3	+1.6	+6.0	+1.9	+1.9
Healthcare Business	5.9	5.8	-0.1	-3.0	-0.2	-0.2	
Cost of Sales	49.1	56.2	+7.1	+14.6	-	-	
SG&A	52.8 (14.2)	48.4 (10.8)	-4.4	-8.2	-	-	
Operating Income	8.8	9.0	+0.2	+1.7	+0.8	+0.4	
Ordinary Income	9.3	9.4	+0.1	+1.0	+0.8	+0.2	
Net Income	6.6	6.9	+0.3	+4.5	+0.8	+0.3	

[Explanation of Variances (Change : revised forecast)]

Net sales: (New drugs in Japan) Sales of Fultiform were strong and sales of Nasonex surpassed expectations.
 (Generic drugs) Sales of the MONTELUKAST AG exceeded expectations.
 Operating Income: Sales were better than expected due to increased revenues.

Mainstay Product Sales

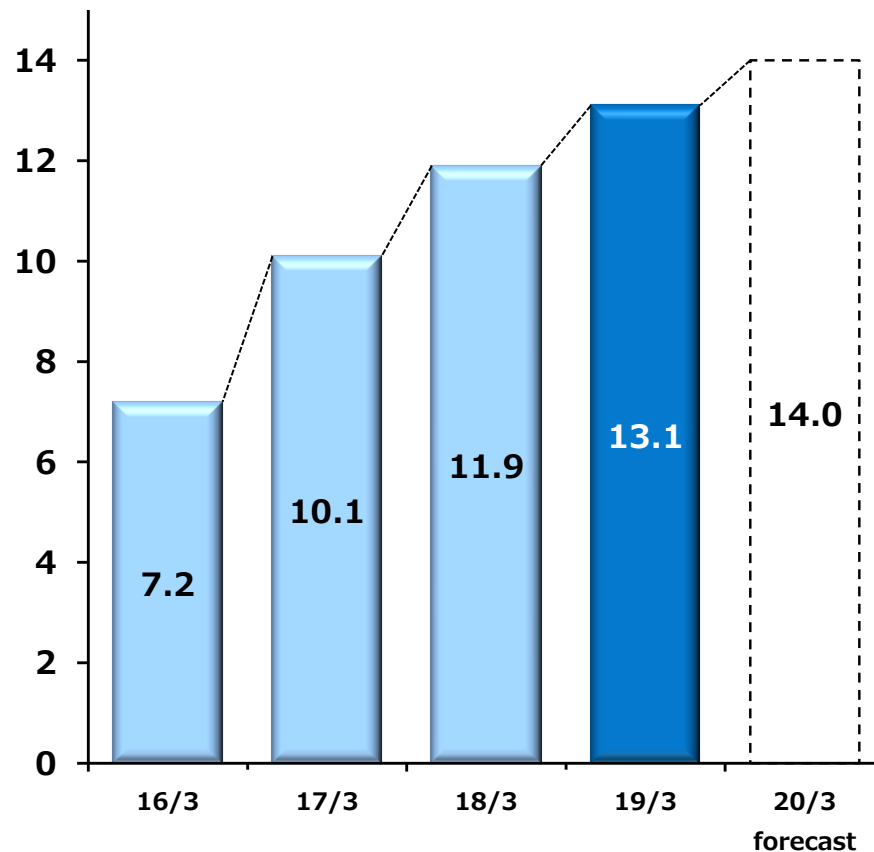
(Units: ¥ billion)

	FY2016	FY2017	Change	Change(%)	Change (revised forecast)	Change (original forecast)
Flutiform (Anti-asthmatic)	11.9	13.1	+1.2	+9.8	+0.8	+0.8
Desalex (allergic rhinitis)	4.9	3.7	-1.2	-24.1	-1.1	-4.4
Kipres for adult (LT receptor antagonist)	8.3	6.2	-2.1	-24.6	+0.2	+0.2
for children	10.5	7.6	-2.9	-27.4	+0.4	+0.4
Nasonex (Spray type allergic rhinitis remedy)	—	12.8	+12.8	—	+2.7	+2.7
Uritos (Kyorin) (Overactive bladder)	7.2	6.6	-0.6	-8.6	-0.2	-0.2
Beova (Overactive bladder)	—	0.7	+0.7	—	-0.1	-0.1
Pentasa (Ulcerative colitis and Crohn's disease treatment)	15.3	13.5	-1.8	-11.4	-0.2	-1.0
Mucodyne (Mucoregulant)	8.7	6.8	-1.9	-22.1	-0.4	-0.4
MONTELUKAST Tablets“KM”	11.7	11.9	+0.2	+1.3	+2.1	+2.1

Trends of mainstay products

Flutiform 【Anti-asthmatic】

(Units: ¥ billion)



■ status of FY2018

◆ ICS/LABA market : expand 4.6%
 ¥115.1bln (FY2017) ⇒ ¥120.3 (FY2018) ※1

● share of Flutiform sales
 11.4% (FY2017) ⇒ 12.2% (FY2018) ※2

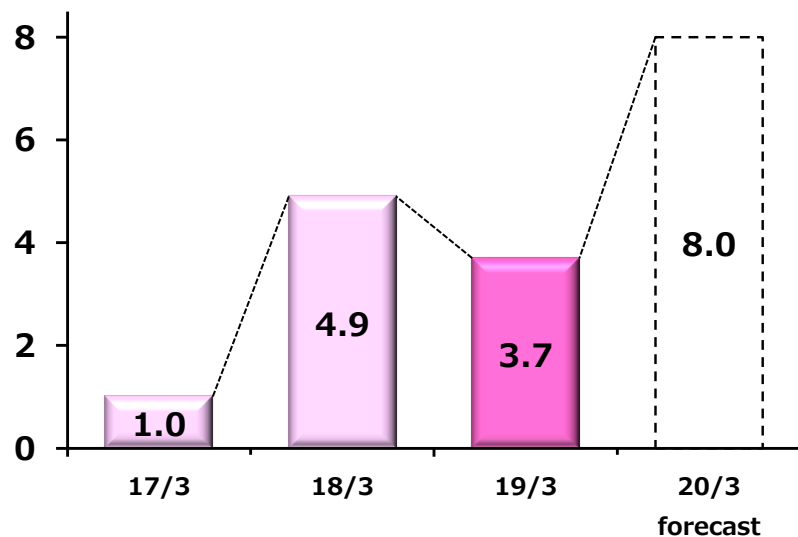
■ Effort for FY2019

- ◆ Aim to establish a first-line drug position in terms of asthma treatments.
- Attract attention to the high clinical impact from a patient with symptoms
 - The agent nicely penetrates and reaches the peripheral airways.
 - Feature the advantages of aerosol-based treatment.
 - People with a weak inspiratory capacity can inhale easily.

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(Units: ¥ billion)

Desalex(Antiallergic Agent)



■status of FY2018

●Antihistamine market : shrink 9.1%

¥178.2bln (FY2017) ⇒ ¥162.1 (FY2018) ※1

●share of Desalex sales

1.5% (2017.1-12) ⇒ 5.3% (2018.1-12) ※2

● Actual sales in the third quarter ended March 31, 2019:
4.8 billion yen

※Supply of the drug is suspended due to the voluntary recall,
effective from January 1, 2019.

We will make an announcement as soon as a decision is reached
regarding resuming the supply.

■effort for FY2019

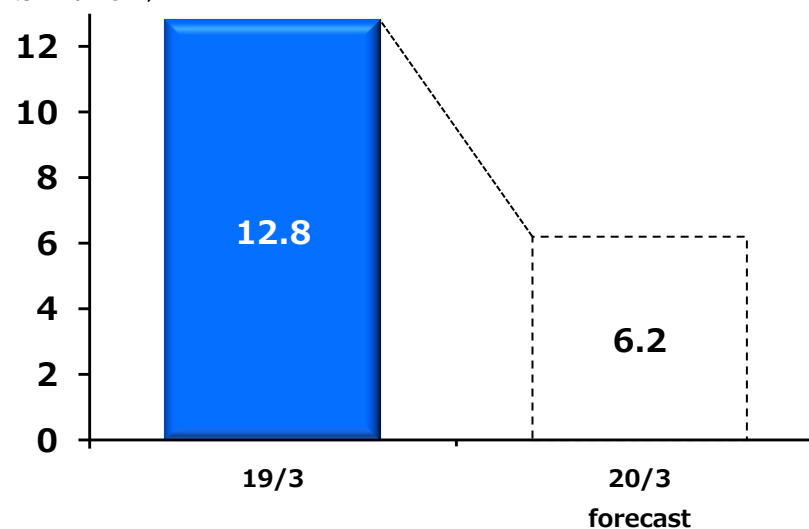
● non-drowsy and effects and usability

● Realization of prescription acquisition rate No.1 in
otolaryngology

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Nasonex (Spray type allergic rhinitis remedy)

(Units: ¥ billion)



■ Acquire domestic exclusive distribution rights (May.2018)

[Sales start] August 2018

[Sales] ¥10.1bln (Forecast) ⇒ ¥12.8bln (FY2018)

● Market scale : 46 billion yen*

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

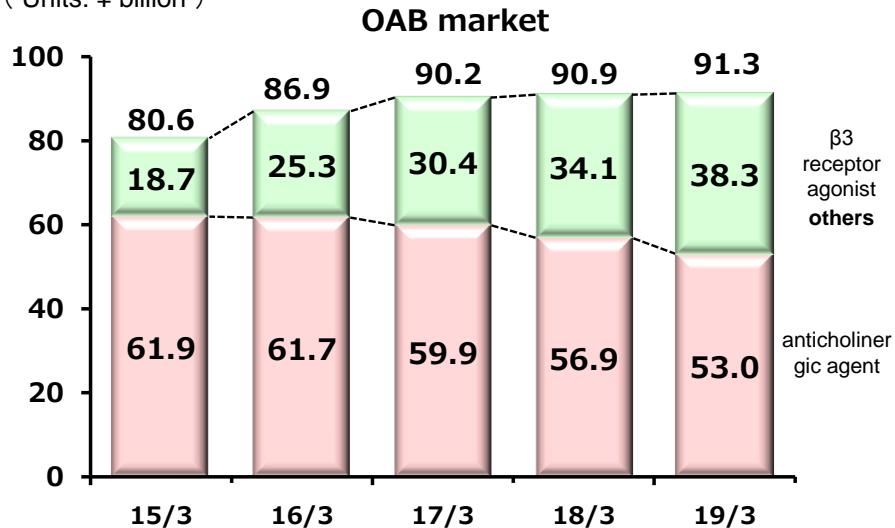
■effort for FY2019

◆Promote sales with a focus on authorized generic drugs (AG)

◆ Increase the market share by expanding sales with both
drugs at otolaryngologists.

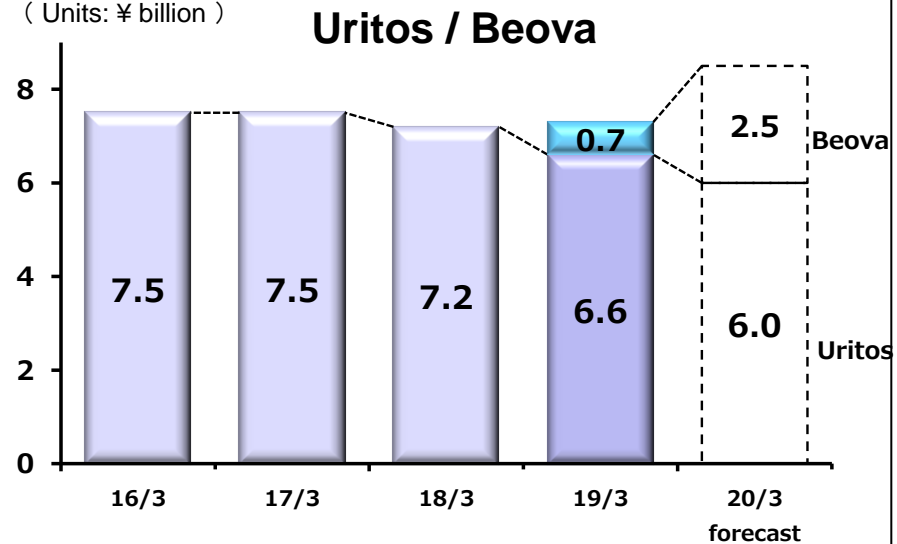
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(Units: ¥ billion)



※(Source: Copyright 2019 IQVIA. IMS –JPM. Unauthorized copying prohibited)

(Units: ¥ billion)



■Beova : Direction of the initiatives

[Popularize the drug to make sure it is chosen as a first-line medicine for OAB treatment.]

- ◆ The drug can be prescribed regardless of differences in OAB symptoms, gender, age and patient background.
- ◆ Emphasize quick and superior effects as well as safety.
- ◆ Increase the number of medical organizations that use the drug for prescriptions and the number of treatments with the drug, with an eye on removing the limit on prescription periods (December).

(Reference information)

Development status overseas: Phase III of Urovant was completed (March 2019).

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

■status of FY2018

●OAB market : expand

¥80.6bln (FY2016) ⇒ ¥91.3 (FY2018) ※1

●share of Uritos sales

8.8% (FY2017) ⇒ 8.3% (FY2018) ※2

●share of Beova sales

0.6% (FY2018) ※3

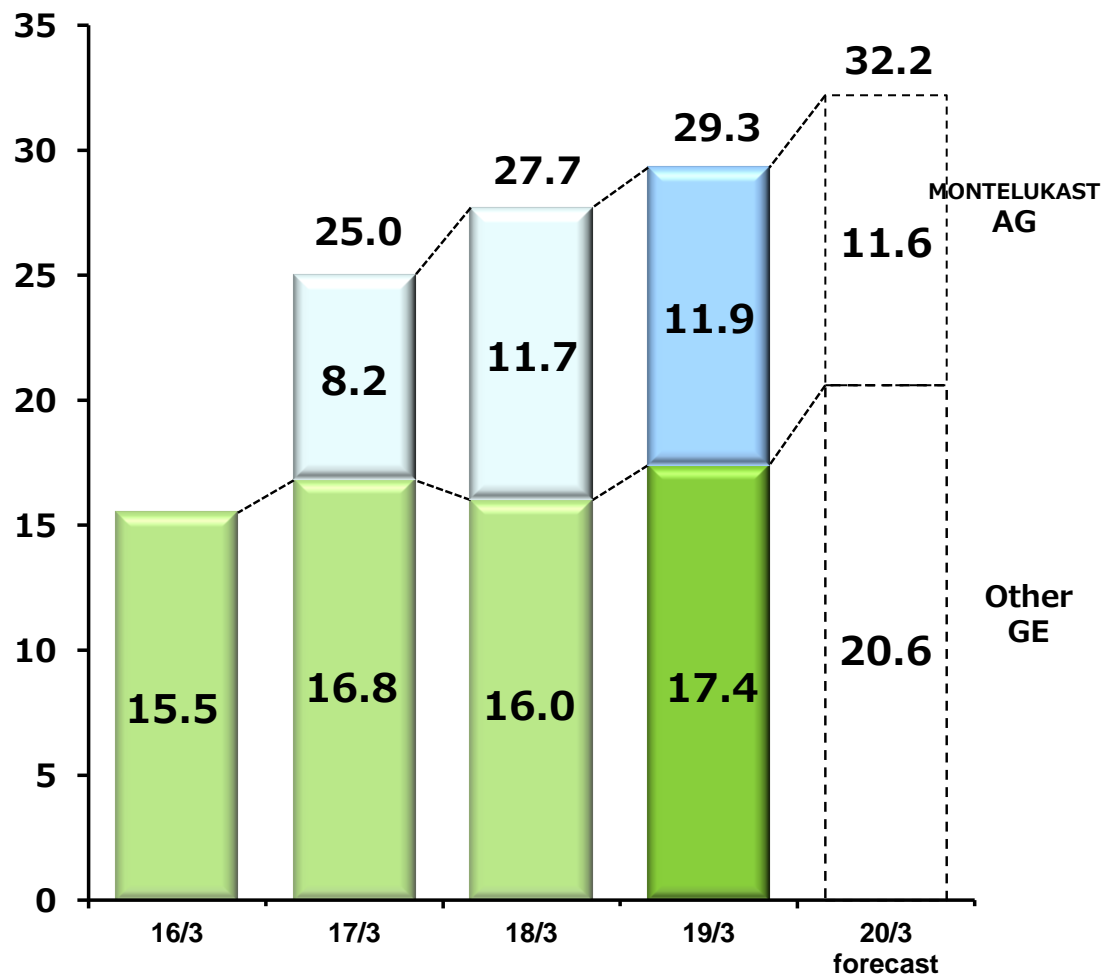
■effort for FY2018

- Succeeded in acceptable product positioning for Uritos (OAB patients with nocturia)
- Offer a new treatment option by promoting Beova

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■ Status of Generic Drugs

(Units: ¥ billion)



■ status of FY2018

- Turnover increase , MONTELUKAST AG: + ¥ 0.2bln
 - ・ Maintain the market share of more than 50% in the GE market.
- Sales of generic drugs except AG (authorized generic) drugs expanded.
 - ・ Generic drugs released in FY2018 contributed to sales growth.

■ effort for FY2019

- **Actions for an authorized generic drug (AG)**
 - ・ Aim to achieve a large market share of more than 50% for MONTELUKAST AG in the GE market
 - ・ Consider acquiring new AGs (Nasonex)
- **Expand sales of strategic products and Supplementary Items**

Consolidated Financial Results and Forecast

Consolidated Financial Results Forecast for the Year Ending March 31, 2020

(Units: ¥ billion)

		FY2018	FY2019 (forecast)	Y/Y		
				Change	Change(%)	
Net sales		113.6	114.1	+0.5	+0.4	
		107.9	108.0	+0.1	+0.1	
Ethical drugs business	Sales of new ethical drugs	78.5	75.8	-2.7	-3.4	
		Japan	77.7	74.4	-3.3	-4.2
		Overseas	0.8	1.3	+0.5	+56.6
	Generic drugs	29.3	32.2	+2.9	+9.8	
Healthcare Business		5.8	6.1	+0.3	+5.9	
Operating Income		9.0	9.1	+0.1	+1.4	
Ordinary Income		9.4	9.6	+0.2	+1.7	
Net Income		6.9	7.1	+0.2	+3.4	

【for reference: year on year】

Net Sales: [decrease] Impact of drug price revision and release of Nasonex
 [increase] Growth in revenues from Flutiform and Beova, launch of new product KRP-AM1977X, and release of Nasonex AG

Gross Profit: The cost of sales ratio declined 1 percentage point from the previous year.

SG&A: R&D expenses remained flat (expected to be 10,900 million yen, or up 100 million from the previous year). The selling expenses and general administration expenses ratio (excluding R&D expenses) increased by almost 1 percentage point year on year.

Forecast of Mainstay Product Sales

(Units: ¥ billion)

	FY2018	FY2019 (forecast)	Y/Y	
			Change	Change(%)
Flutiform (Anti-asthmatic)	13.1	14.0	+0.9	+7.6
Desalex (allergic rhinitis)	3.7	8.0	+4.3	+115.1
Kipres for adult (LT receptor antagonist)	6.2	4.5	-1.7	-26.5
for children	7.6	6.1	-1.5	-19.2
Nasonex (Spray type allergic rhinitis remedy)	12.8	6.2	-6.6	-51.1
Uritos (Kyorin) (Overactive bladder)	6.6	6.0	-0.6	-8.0
Beova (Overactive bladder)	0.7	2.5	+1.8	+242.6
Pentasa (Ulcerative colitis and Crohn's disease treatment)	13.5	12.0	-1.5	-11.4
Mucodyne (Mucoregulant)	6.8	6.0	-0.8	-10.2
MONTELUKAST Tablets "KM"	11.9	11.6	-0.3	-2.1

Status of development pipeline

Drug Development Pipeline: Progress in FY2018



progress in 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 2018/6		2017/6	Preparation	
Infections	KRP-AM1977X	→	→	→	2017/4		
	KRP-AM1977Y	→	→	→		Preparation	
Urological	KRP-116D			2017/3			
	KRP-N118 (SK-1404)		Ph II Start 2018/8				

【 Licensing development 】

開発コード	導出先	開発段階	特徴
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	Implementing licensing activities	Ph I	Sphingosine-1-Phosphate Receptor Agonist Therapy area GvHD
	Because Novartis (licensee) decided to discontinue development of KRP-203 for strategic reasons, Kyorin receive the return of development rights.		

Drug Development Pipeline: Progress in FY2019



progress in FY19

	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 2018/6		2017/6	Preparation	Expecting to create an Application in FY19
Infections	KRP-AM1977X				2017/4		FY19 Expected Release
	KRP-AM1977Y					Preparation	Expecting to create an Application in FY19
Urological	KRP-116D				2017/3	Preparation	Expecting to create an Application in FY19
	KRP-N118 (SK-1404)		Ph II Start 2018/8				

※ MK-7264, a drug for chronic coughing: MSD is working on Phase III development. Concluded a memorandum of understanding for sales collaboration (2019/5).

【 Licensing development】

開発コード	導出先	開発段階	特徴
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	Implementing licensing activities	Ph I	Sphingosine-1-Phosphate Receptor Agonist Therapy area GvHD
	Because Novartis (licensee) decided to discontinue development of KRP-203 for strategic reasons, Kyorin receive the return of development rights.		

Status of Development

- Phase III clinical trial: Completed ◆ Application in preparation

Study: Open-label, active-controlled, cross-over study in children with bronchial asthma

Disease: Bronchial asthma in children (patients with bronchial asthma aged ≥ 5 , < 16 years)

Target sample size: 70 patients

Dosage and administration: Two inhalations (puffs) of Fultiform (50/5 μg), twice daily

[Primary endpoint] mPEF: Change from baseline (mean mPEF values in seven days prior to visit for treatment period-1)



Study Results

In the Phase III clinical study, non-inferiority of Fultiform to the control (a fixed-dose combination of fluticasone and salmeterol) was validated.

No safety issue was confirmed in a long-term study (open-label, uncontrolled) concurrently-conducted in children with bronchial asthma.

KRP-116D, a treatment for interstitial cystitis

(active ingredient: dimethylsulfoxide)

Status of Development

- **Phase III clinical trial: Completed** ◆ **Application in preparation**

*Under development as unapproved or off-labeled drugs with high medical needs

Study: A multicenter, randomized, double-blinded, placebo-controlled, parallel-group study

Disease: Interstitial cystitis

Target sample size: 90 patients

Dosage and administration: Instillation of 50 mL of KRP-116D into the bladder every two weeks

[Primary endpoint] Efficacy; Interstitial Cystitis Symptom Index (ICSI)

Note: Designation as an orphan drug

Study Results

The superiority and safety of KRP-116D to placebo was confirmed in the Phase III clinical study. (Superiority of KRP-116D to placebo was demonstrated for the first time in the world.)

**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.

Efforts on first-in-class drug discovery

Building a system for the creation of innovative new drugs

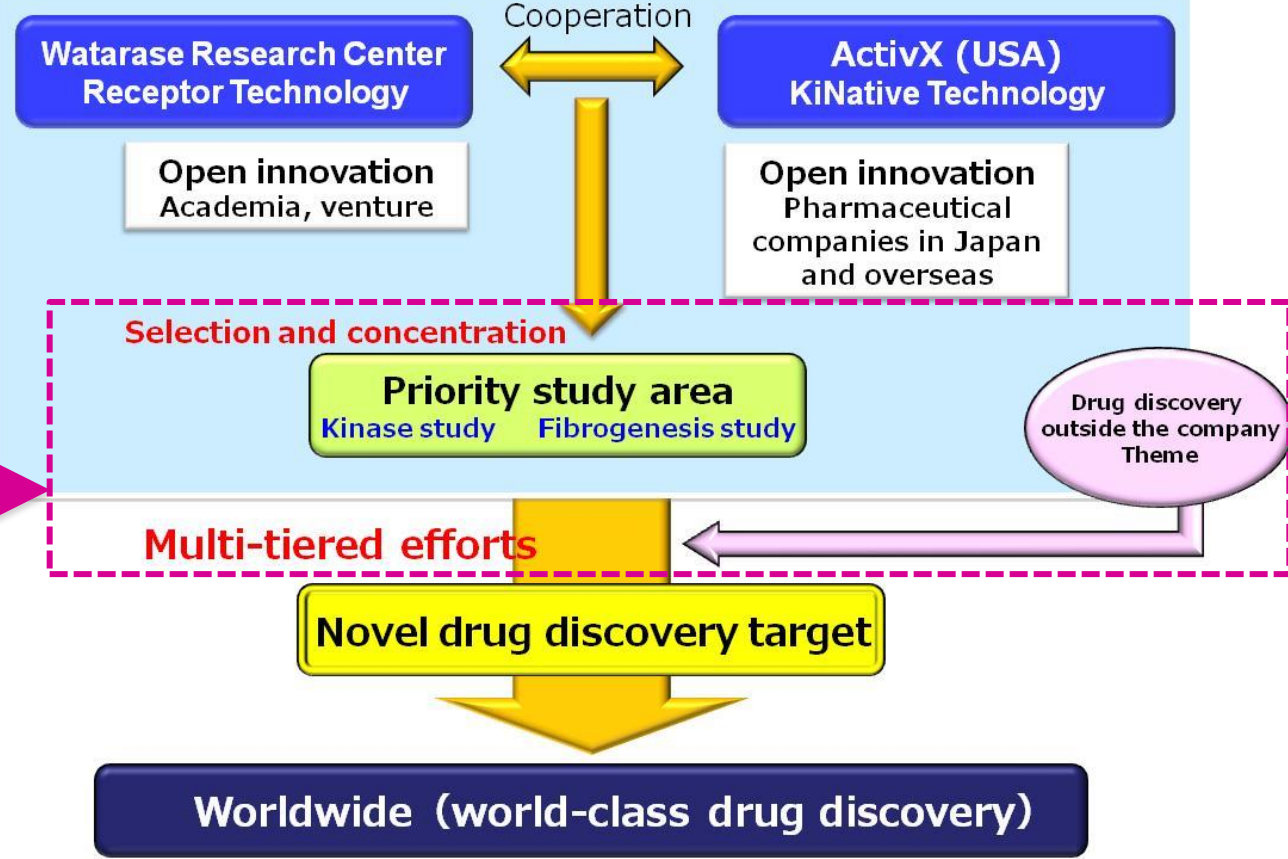
Joint Studies

- Kyoto University**
Department of Drug Discovery for Lung Diseases
- Institute of Microbial Chemistry**
Search in antibacterial drug field
- **Hebrew University**
Development of drugs for respiratory diseases

Strengthening the function of planning drug generation

Restructuring organization

Move on with oligonucleotide therapeutics as a new modality



Priority strategy: Increase ratio of new drug group

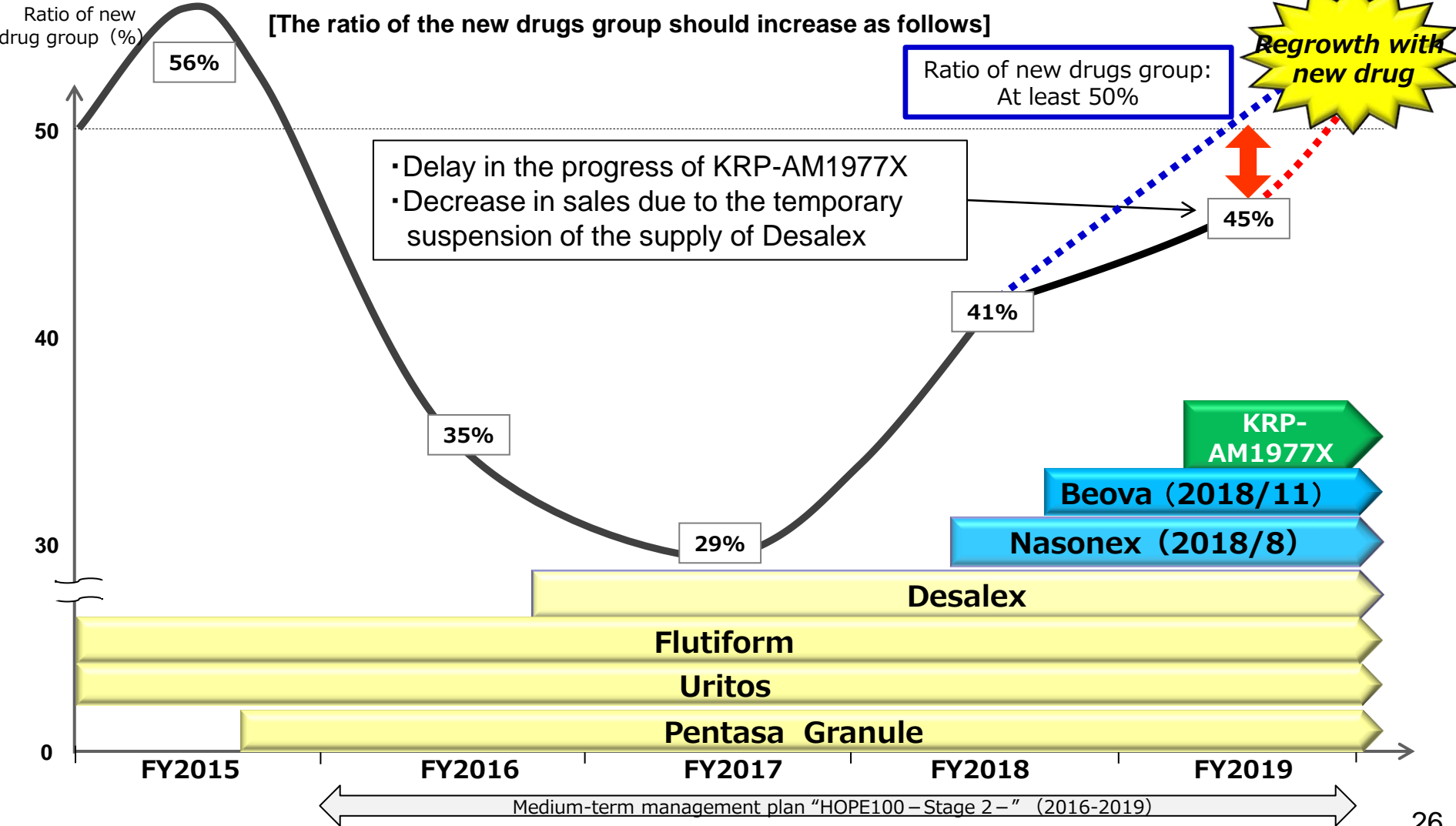


Accelerate regrowth with new drug group and new products

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- Maximize the dissemination of Flutiform, Desalex, and Beova.
- Launch and disseminate KRP-1977X.

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



Market creation through the launch of new ethical drugs

Medium-term management plan “HOPE100 – Stage 2 – ” (2016-2019)

Launch four new products during the stage 2 period and popularize them and Flutiform as much as possible

FY2016~		Current State	~FY2019	~FY2023	Vision
Flutiform	Market share 7% (FY2015) Market share 12% 注1 (FY2018)	ICS/LABA : ¥120bln 注2	Aim to launch pediatric drugs (application will begin in 2019)		Quantity-based market share of ICS/LABA combination drug market: 30%
Beova	Launch (2018/11)	OAB : ¥90bln 注2	The limits on prescription periods were removed (December 2019)		Percentage of patients that take prescriptions: 30% or higher
Desalex	Launch (2016/11)	Antihistamine : ¥160bln 注2	Aim to get the highest prescription acquisition rate in the otolaryngology area after the resumption of supply		Top share in the Antihistamine market
KRP-AM1977X	Application	Antibacterial agent (oral) : ¥110bln (Injection) : ¥110bln 注2	• KRP-AM1977X Aim to launch (2019) • KRP-AM1977Y Aim to launch (application will begin in 2019)		Highest percentage of respiratory and otolaryngology patients that take prescriptions
KRP-AM1977Y	Preparing application				

OAB market: Anticholinergic agents and β3 adrenoceptor agonists

Antibacterial agent market: includes all systemic antibacterial agents and children in all markets.

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AG strategy and Strengthening of ability to perform business

➤ AG strategy

Montelukast AG



**Maintain the quantity-based share
of more than 50% in the GE market**

Mometasone AG



Aim to launch (FY2019)

Consider acquiring new AGs

■ Strengthening of ability of KYORIN Rimedio Co., Ltd. to perform business

➤ Strengthening the competitiveness of products developed in-house

**Establishment of Takaoka
Pharmaceutical Technology
Innovation Center
(opened in July 2017)**



**Aim to establish an organizational
system under which eight
ingredients are launched on an
annual basis**

Consolidation of the Group's production functions

Change of the cost structure by ensuring optimization within the Group

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

Noshiro plant (Akita)



Inami plant (Toyama)



Shiga plant (Shiga)



- ◆ Control outsourcing expenses by equalizing the manufacturing capabilities of each factory
- ◆ Facilitate efficient operation through the flexible transfer of employees among factories.
- ◆ Use existing facilities more effectively and reduce capital expenditure for building new facilities

Reduction of approximately 300 million yen in the first fiscal year (FY2018)

Expected effects of reorganization: total cost reduction of approximately 1,000 million yen by 2023.

Aim to be the next core business



Characteristics

- Rapid detection of genes based on the technology of ultrafast quantitative PCR* (5-15 minutes)
- High-sensitivity detection is possible with a trace amount of the sample immediately after infection
- A compact, desktop PCR device eyeing POCT*

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



Up to 4 Detection Units can be added and the simultaneous test of multiple samples is possible

- ※1 PCR (Polymerase Chain Reaction): A technique of selectively amplifying DNA arrangements.
- ※2 POCT (Point of Care Testing): Testing carried out by a healthcare worker at a patient's bedside.

[GeneSoC®] ultrafast gene quantitative system

- A measurement chip and a reagent for research: to be released in **the second half of FY2019**.
- Extracorporeal diagnostic agent: Aim to release a drug in 2021.

Continuous Growth

Medium-term management plan “HOPE100 – Stage 2 –” (2016-2019)

<Target value>	Factor	<FY2019 (Forecast) >
<p>the average annual growth rate : 3% or more</p> <p>the consolidated operating income margin : 15% or more</p>	<p>■ the new drug business (in Japan)</p> <ul style="list-style-type: none"> • Delay in the progress of KRP-AM1977X • Decrease in sales due to the temporary suspension of the supply of Desalex <p>■ the business of drug discovery (overseas development)</p> <ul style="list-style-type: none"> • Lower-than-expected income from royalties. (Discontinuation of the development of KRP-203 on the part of the licensee.) <p>[Changes in systems and business circumstances]</p> <p>■ Dramatic reform of the NHI drug price scheme</p> <ul style="list-style-type: none"> • Review of the Price Maintenance Premium • Frequent drug prices revisions 	<p>the average annual growth rate : -1.1%</p> <p>the consolidated operating income margin : 8%</p>

For continuous growth (Refinement of pharmaceutical Business)

<p><Drug Discovery></p> <p>■ Initiatives for first-in-class New drug discovery</p> <ul style="list-style-type: none"> • Establishment of system for continual generation of innovative new drugs 	<p><New Drug Business></p> <p>■ Increase in the Ratio of New Drugs Group</p> <ul style="list-style-type: none"> • Make the four new drugs (including those developed in-house) the driving force 	<p>< Generic Drugs Business ></p> <p>■ Promotion of Generic Drugs Business by Making the Most of Its Characteristics</p> <ul style="list-style-type: none"> • promotion of AG strategy 	<p>< New businesses ></p> <p>■ Development of the diagnostic business and establishment of a foundation</p>
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Shareholder Returns

Basic Policy

- While maintaining the sound financial base, we aim to improve the capital efficiency through growth investment and returns to shareholders.
- We will maintain stable dividends taking DOE (Dividend on Equity ratio) into account.

Dividend per share for fiscal 2018 (estimate): ¥75 (including interim dividend of ¥30)

Dividends

	FY2016	FY2017	FY2018※	FY2019 (forecast)
Dividend per share (Yen)	¥58 (Year-end ¥38)	¥58 (Year-end ¥38)	¥75 (Year-end ¥45)	¥75 (Year-end ¥45)
Consolidated payout ratio(%)	59.3%	65.9%	72.6%	61.4%

※The year-end dividend of 45 yen in the fiscal year ending March 2019 will be decided at in the Board Meeting Scheduled for May 22.

**Develop growth potential
and
follow a growth path**