Interim Term Financial Results Ended September 2018

November 6 , 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**
- **Basic Policy and initiatives related to capital policy**

Outline of Consolidated Financial Results

Outline of Consolidated Financial Results for the Interim Term Ended September 2018

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(unit : ¥billion)	Sep/17	**Sep/18**	**Change**	**Change(%)**	**Change (forecast)** Announced on May 10, 2018
Net Sales	50.8	**50.4**	−0.4	−0.8	+0.2
Operating Income	1.4	**2.9**	+1.5	+97.6	+1.0
Ordinary Income	1.7	**3.2**	+1.5	+88.0	+1.0
Net Income	1.2	**2.2**	+1.0	+78.8	+0.7

We released a revision to our second-quarter financial results forecast on November 2, 2018 but these comparisons with the forecast show differences from the forecast announced on May 10, 2018.

Segment Sales and Breakdown of Gain and Loss

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(unit : ¥billion)			Sep/17	Sep/18	Change	Change (%)	Change (forecast) Announced on May 10, 2018
Net Sales			50.8	**50.4**	**−0.4**	**−0.8**	+0.2
Ethical drugs business			48.0	47.6	−0.4	−0.8	+0.2
	Sales of new ethical drugs		35.0	34.0	−1.0	−2.7	−0.1
		Japan	34.4	33.4	−1.0	−3.0	−0.2
		Overseas	0.5	0.6	+0.1	+15.5	+0.1
	Generic drugs		13.0	13.6	+0.6	+4.2	+0.4
Healthcare Business			2.8	2.8	0	−0.1	0
Cost of Sales			23.1	**23.8**	**+0.7**	**+2.7**	−
SG&A			26.2	**23.7**	**−2.5**	**−9.3**	−
Operating Income			1.4	**2.9**	**+1.5**	**+97.6**	+1.0
Ordinary Income			1.7	**3.2**	**+1.5**	**+88.0**	+1.0
Net Income			1.2	**2.2**	**+1.0**	**+78.8**	+0.7

We released a revision to our second-quarter financial results forecast on November 2, 2018 but these comparisons with the forecast show differences from the forecast announced on May 10, 2018.

Highlights of Business Performance:①Net sales

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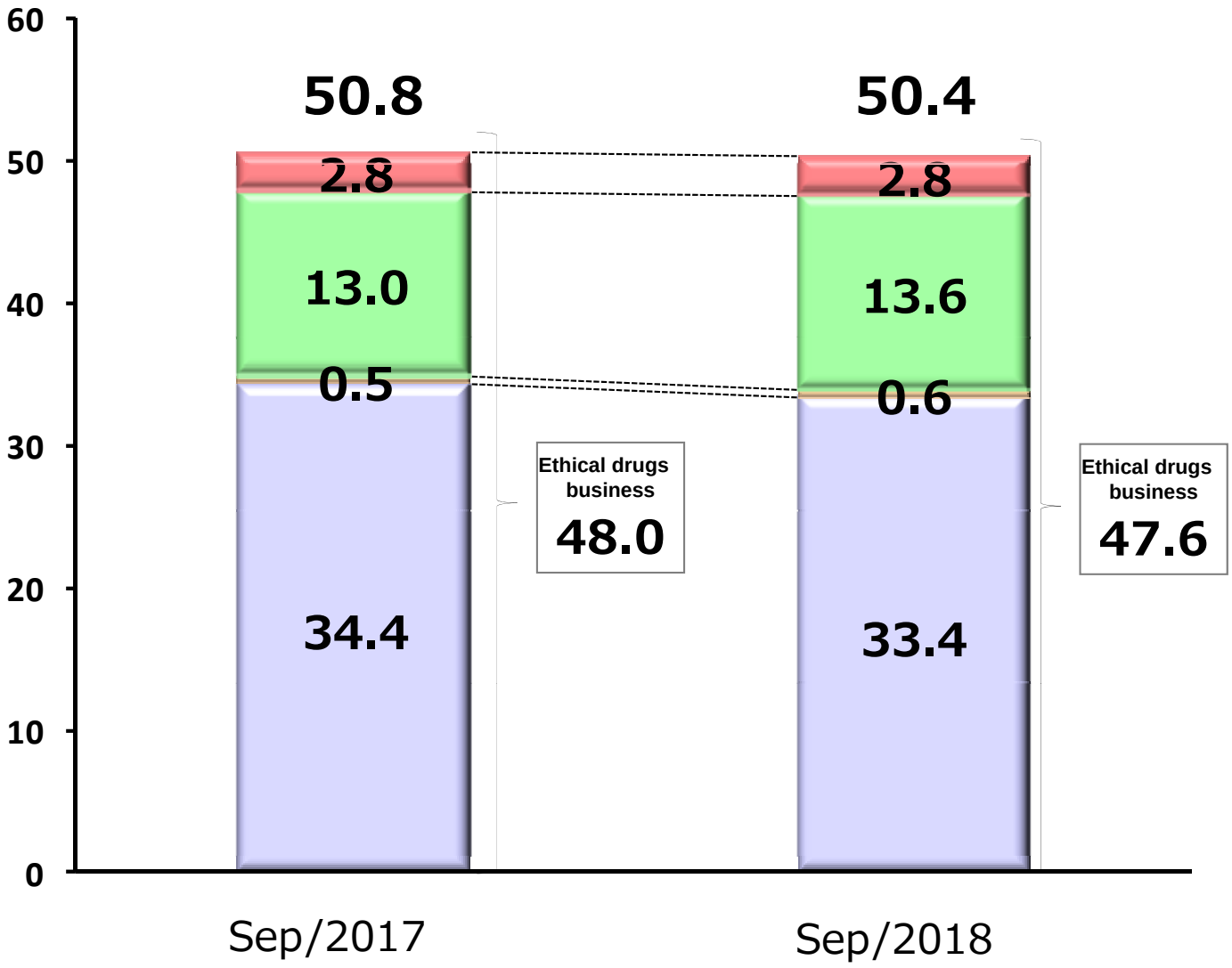
（Units: ¥billion）



【 Net Sales ¥－0.4bin 】

Healthcare Business ¥±0

・Growth of RUBYSTA and Milton

【 Ethical drugs business－0.4】

Generic drugs ¥＋0.6bin

・Increase of MONTELKAST AG sales
・ Launches of new Generic Drugs

New ethical drugs (overseas) ¥＋0.1bin

・Increase of Gatifloxacin sales

New ethical drugs(Japan) ¥－1.0bin

・Despite steady growth in Flutiform and Desalex sales
・Contribution sales of Nasonex
・Decreased in prescriptions of long-listed drugs.

Highlights of Business Performance : ②Operating Income

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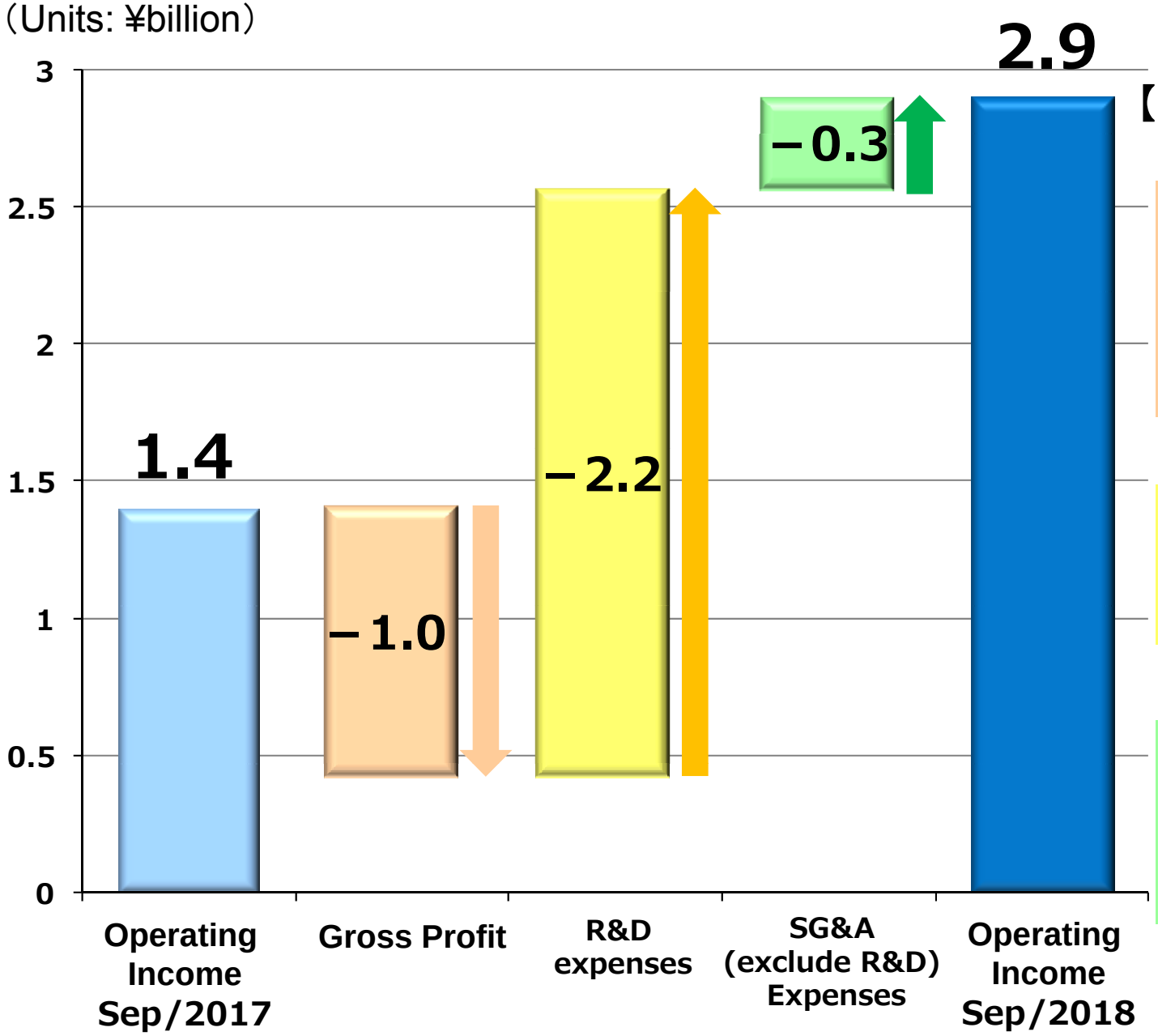
（Units: ¥billion）



【 Operating Income＋￥1.5bin 】

Gross Profit decreased

Net Sales decreased ¥0.4billion year on year.
Cost of sales ratio increased 1.6%.
- Drug price revisions
- Increase of sales of Generic drugs

R&D expenses decreased

- **R&D expenses decreased**
  ￥7.2bin （Sep/2017）⇒￥5.0bin （Sep/2018）

SG&A (exclude R&D)Expenses decreased

- Decrease of Labor costs, , Selling costs.
  ￥19.0bin （Sep/2017）⇒￥18.7bin （Sep/2018）

Highlights of Business Performance

:③Change (forecast)

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(unit : ¥billion)			Sep/17	Sep/18	Change	Change (%)	Change (forecast) Announced on May 10, 2018
Net Sales			50.8	**50.4**	**−0.4**	**−0.8**	+0.2
Ethical drugs business			48.0	47.6	−0.4	−0.8	+0.2
	Sales of new ethical drugs		35.0	34.0	−1.0	−2.7	−0.1
		Japan	34.4	33.4	−1.0	−3.0	−0.2
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	Generic drugs		13.0	13.6	+0.6	+4.2	+0.4
Healthcare Business			2.8	2.8	0	−0.1	0
Cost of Sales			23.1	**23.8**	**+0.7**	**+2.7**	−
SG&A			26.2	**23.7**	**−2.5**	**−9.3**	−
Operating Income			1.4	**2.9**	**+1.5**	**+97.6**	+1.0
Ordinary Income			1.7	**3.2**	**+1.5**	**+88.0**	+1.0
Net Income			1.2	**2.2**	**+1.0**	**+78.8**	+0.7

■ **Net Sales and Operating Income: Difference from Original Forecast**

Net Sales: In sales of new ethical drugs in Japan, although sales of main product Flutiform were higher than forecast, sales of long-listed drugs and other products were less than forecast.In sales of generic drugs, mainly sales of MONTELUKAST AG were strong.

SG&A: SG&A were less than forecast due to cost reductions and postponement of recording of certain expenses *R&D expenses 5 billion yen (forecast of 5.5 billion yen)

Main Product Sales Update

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(unit : ¥billion)	Sep/17	Sep/18	Change	Change(%)	Change (forecast) Announced on May 10, 2018
Flutiform (Combination drug for asthma treatment)	5.4	**6.1**	+0.7	+12.4	+0.4
Uritos (Kyorin) (Overactive bladder)	3.6	**3.5**	−0.1	−3.7	+0.1
Desalex (Antiallergic Agent)	0.9	**2.8**	+1.9	+229.7	−0.2
Kipres for adult (LT receptor antagonist)	3.9	**2.9**	−1.0	−25.9	0
Kipres for children (LT receptor antagonist)	5.1	**3.3**	−1.8	−35.6	+0.4
Pentasa (Ulcerative colitis and Crohn's diseasetreatment)	8.0	**7.1**	−0.9	−10.4	−0.2
Mucodyne (Mucoregulant)	3.9	**3.1**	−0.8	−21.0	−0.1
Nasonex (Spray type allergic rhinitis remedy)	−	**1.3**	+1.3	−	0
MONTELUKAST Tablets "KM"	5.0	**5.3**	+0.3	+5.5	+0.5

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Trends of mainstay products and Generic drugs

■ Respiratory/Otolaryngology

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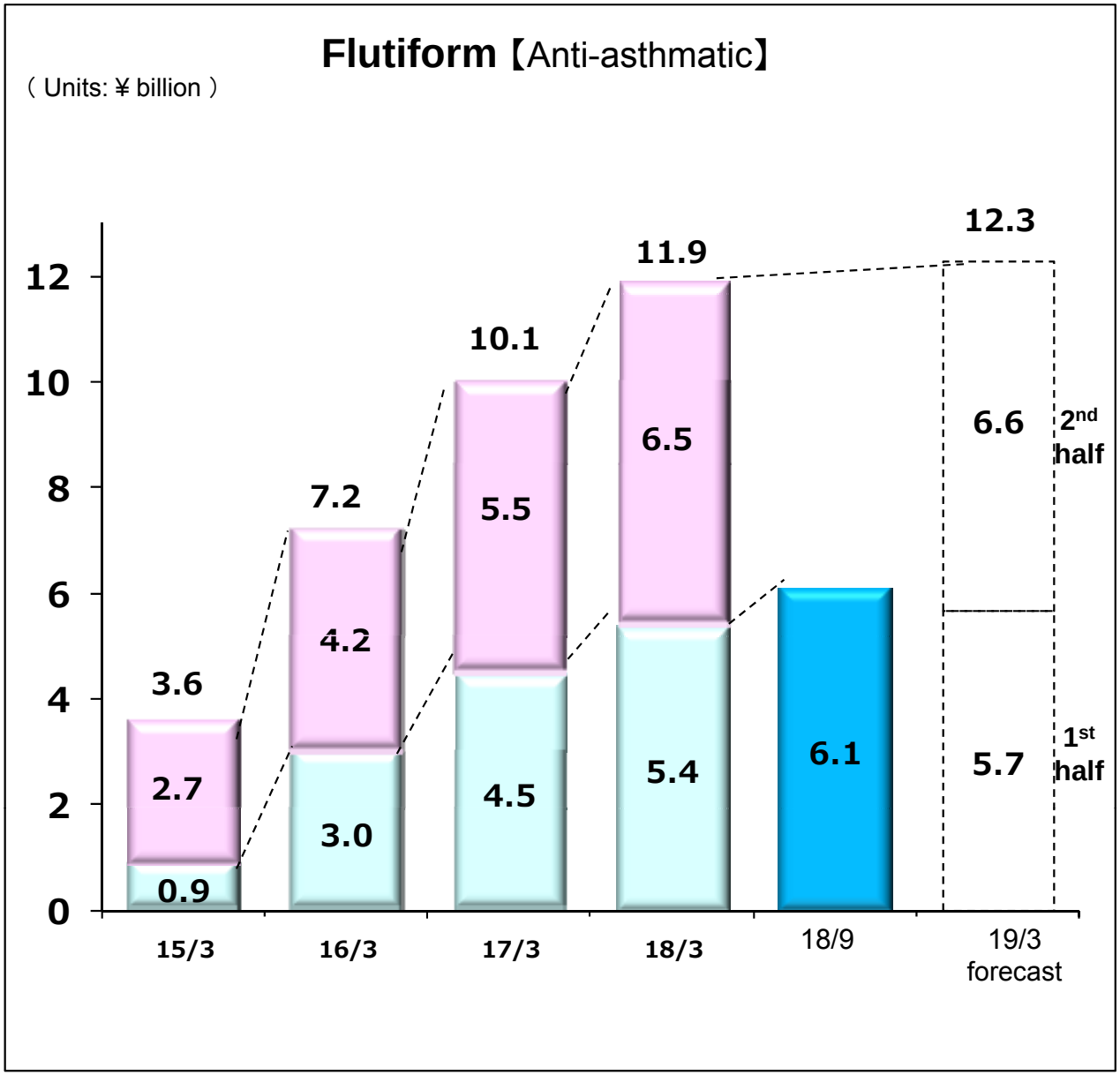

■ Status in first half 2018

●ICS/LABA market：expand 2.7%
¥55.2bln（FY17 first half）⇒ ¥56.7bln（FY18 first half） ※1

●share of Flutiform sales
11.0%（FY17 first half ）⇒ 11.9%（FY18 first half ）※2

【price rivision 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.

■ Respiratory/Otolaryngology

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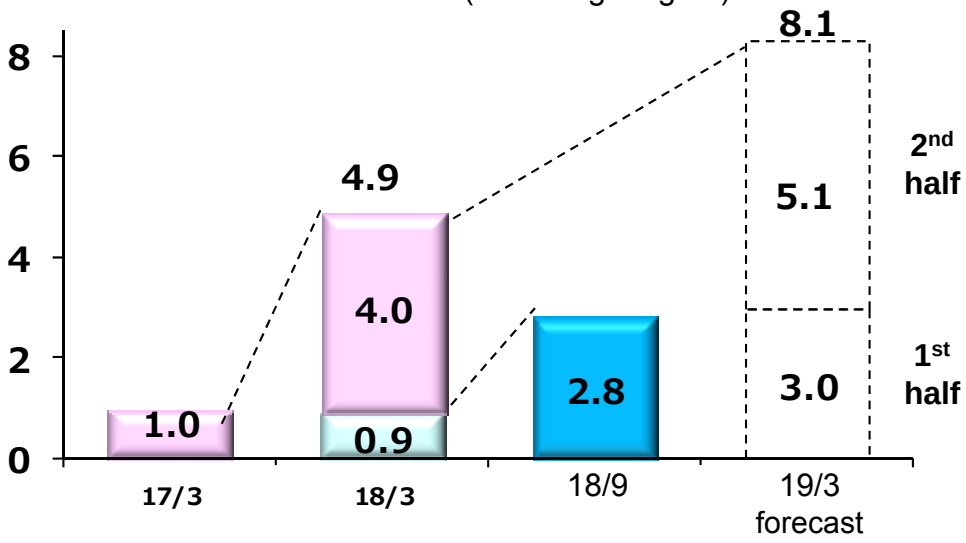
（Units: ¥ billion）

Desalex(Antiallergic Agent)



■ Status in first half 2018

- **Antihistamine market： shrink 11.1%**
  ¥77.4bln（FY17 first half）⇒ ¥68.8bin（FY18 first half）※1
- **share of Desalex sales**
  1.3%（FY17 first half）⇒ 5.0%（FY17 first half）※2
  【price rivision rate ▲5.6%】

■ Effort for FY2018

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

Nasonex（Spray type allergic rhinitis remedy）

■ Acquire domestic exclusive distribution rights (May.2018)

■ August 2018 sales start

【Sales Results】 1.3 billion yen
(Fiscal year ending September 2018)

[Sales forecast] 10.1 billion yen
(fiscal year ending March 2019)

■ Status in first half 2018

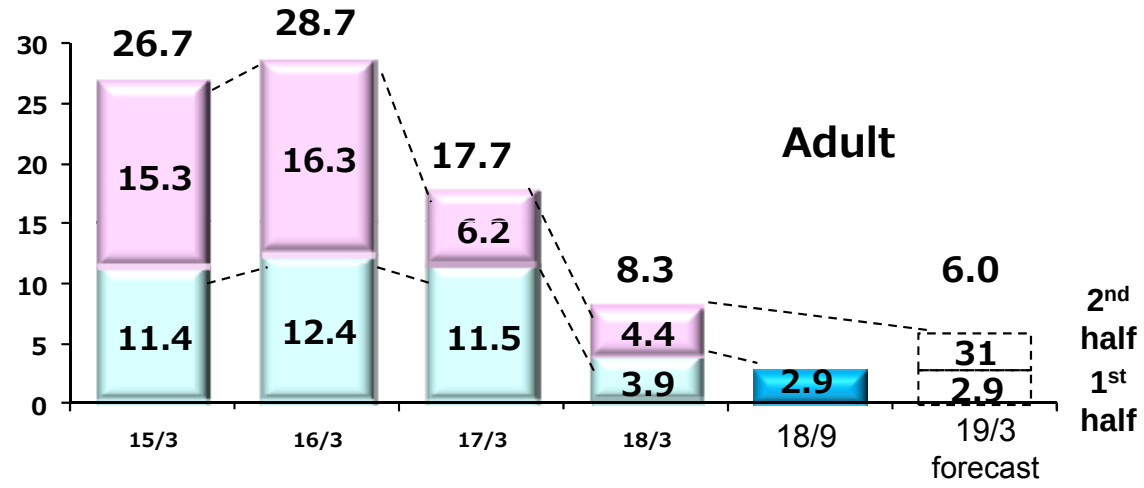
- **Spray type allergic rhinitis remedy market : expand 5.8%**
  ¥14.6bin（FY17 first half）⇒ ¥15.5bin（FY18 first half）注1
- **share of Nasonex sales**
  36.4%（FY17 first half）※2

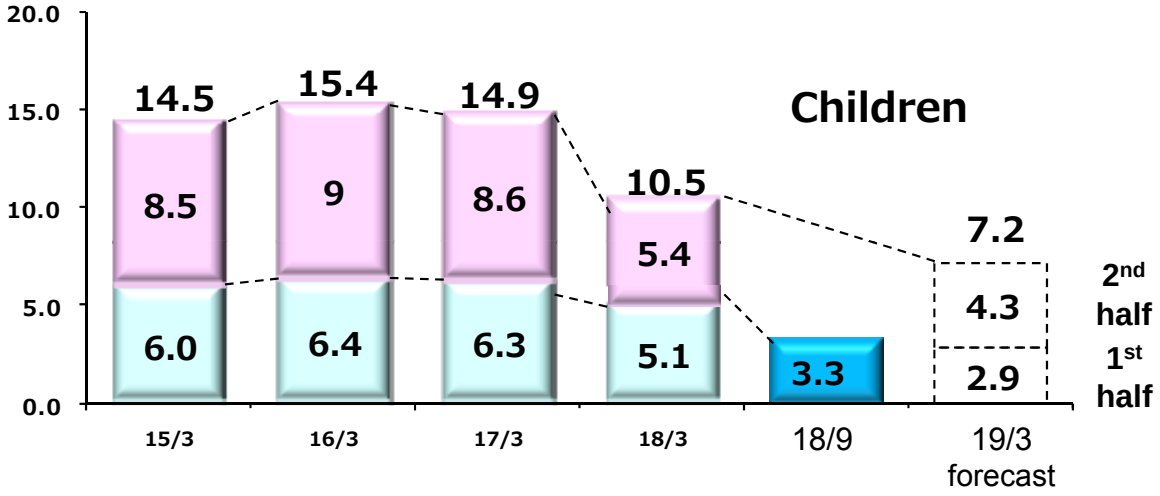
■ Effort for FY2018

- **Desalex along with the Kipres (montelukast AG), aims to expand market share in otolaryngology.**

■ Respiratory/Otolaryngology

Kipres 【Bronchial asthma and allergic rhinitis treatment】





■ Status in first half 2018

- **LT antagonists market：shrink 21.4%**
  ¥43.0bin（FY17 first half）⇒ ¥33.8bin（FY18 first half）※1
- **share of Kipres sales**
  22.5%（FY17 first half）⇒ 22.5%（FY18 first half）※2

【price rivision rate ▲10.2%】

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■Urology

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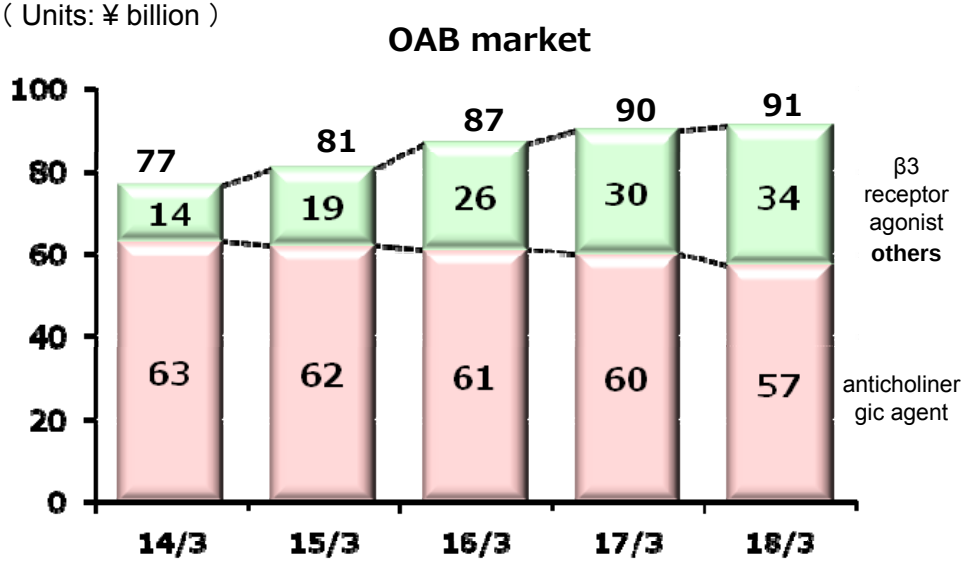
（Units: ¥ billion）



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■**OAB market expand**

¥77.0bln（FY2013）⇒ ¥91.0bin（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.

Acquisition of manufacturing approval for **Beova** (September)

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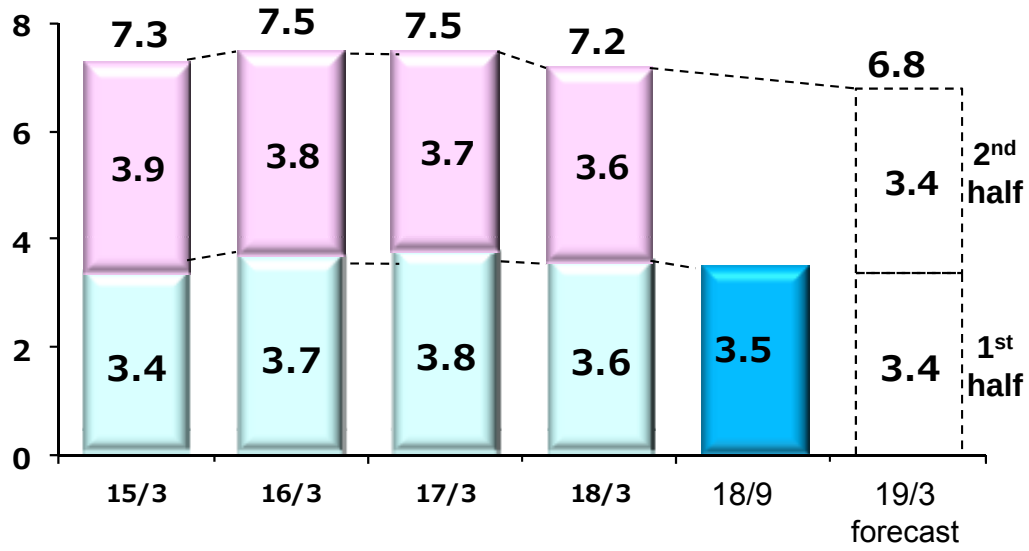
（Units: ¥ billion）**Uritos**（Overactive bladder）



■ **Status in first half 2018**

●**OAB market : flat**

¥44.8bln（FY17 first half）⇒ ¥44.3bin（FY18 first half）※1

●**share of Uritos sales**

8.9%（FY17 first half）⇒ 8.6%（FY18 first half）注2

【price rivision rate ▲5.9%】

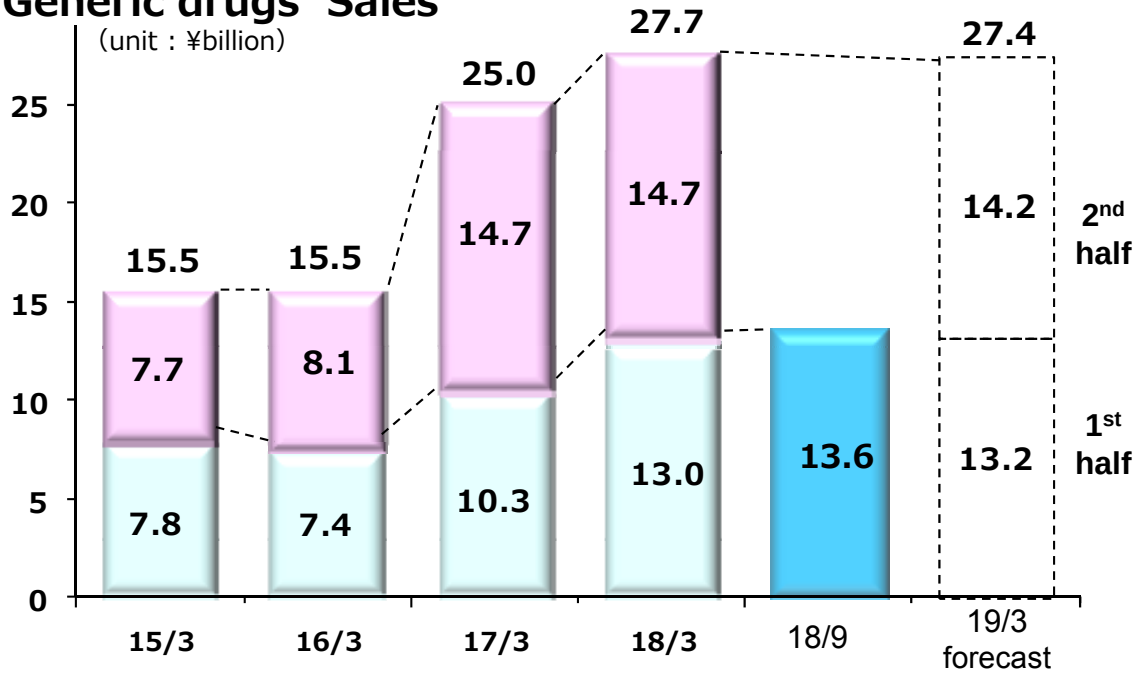
■ **Effort for FY2018**

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

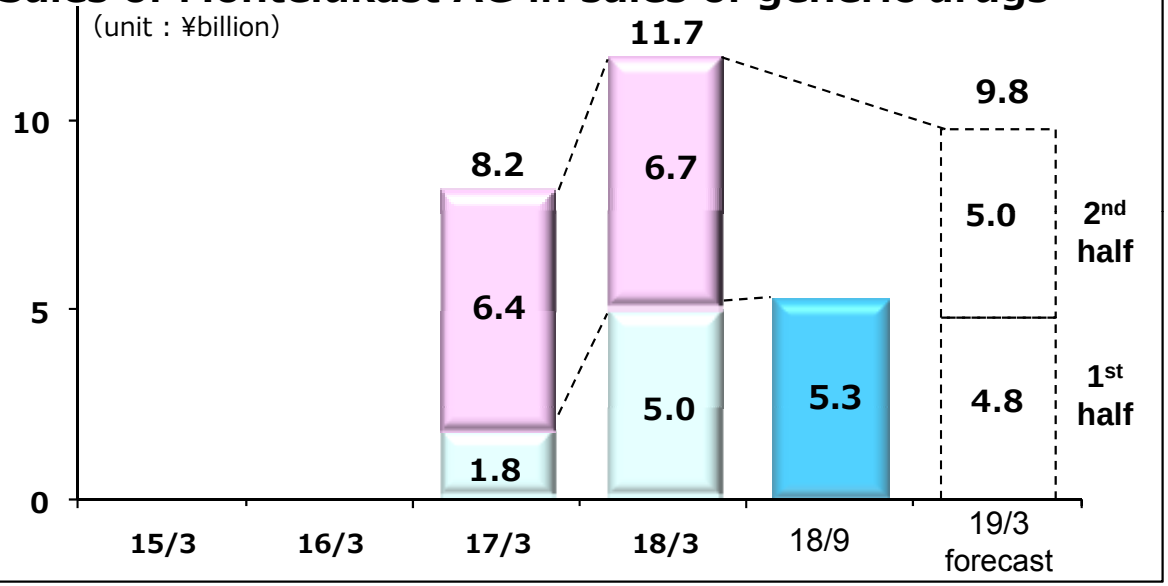
・Promotion of prescription based on extensive evidence

■Status of Generic Drugs

■Generic drugs Sales



■Sales of Montelukast AG in sales of generic drugs



■ Status in first half 2018

●MONTELUKAST AG increase ￥5.3bin(＋￥0.3bln)
【 price rivision rate ▲18.0%】

●2018 June supplementary Item
= ILUAMIX, OLMESARTAN etc.

■ 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

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（Units: ¥ billion）

			FY2017	FY2018 (forecast)	Y/Y Change	Y/Y 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
		Overseas	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

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（ 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 diseasetreatment)	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

Status of development pipeline

Drug Developmet Pipeline: Progress in FY2017, schedule of FY2018

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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	Ph Ⅱ start			
	KRP-108P			2017/6		
Infections	KRP-AM1977X				2017/4	FY19 Expected Release
	KRP-AM1977Y				preparation	
Urological	KRP-114V				2017/9	FY18 Expected Release
	KRP-116D					
	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	Licensee	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	Derivation activity restart	**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 Developmet Pipeline: Progress in FY2017, schedule of FY2018

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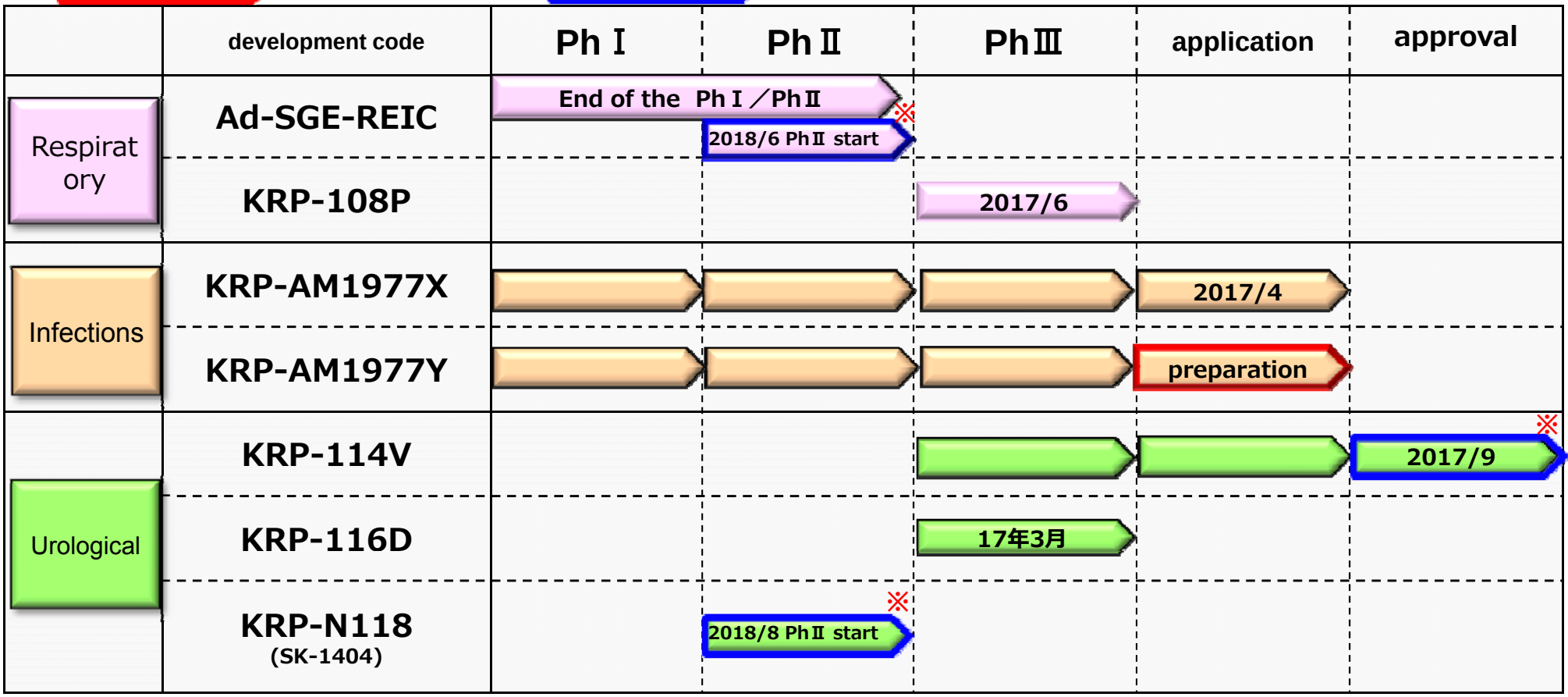
schedule of FY18　progress in FY18 2Q　※ Changes from the previous announcement(July 31 2018)



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

Compound/Code	Licensee	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	Derivation activity restart	**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.		

Beova Tablets 50 mg

(selective β3-adrenergic receptor agonist for the treatment of overactive bladder)

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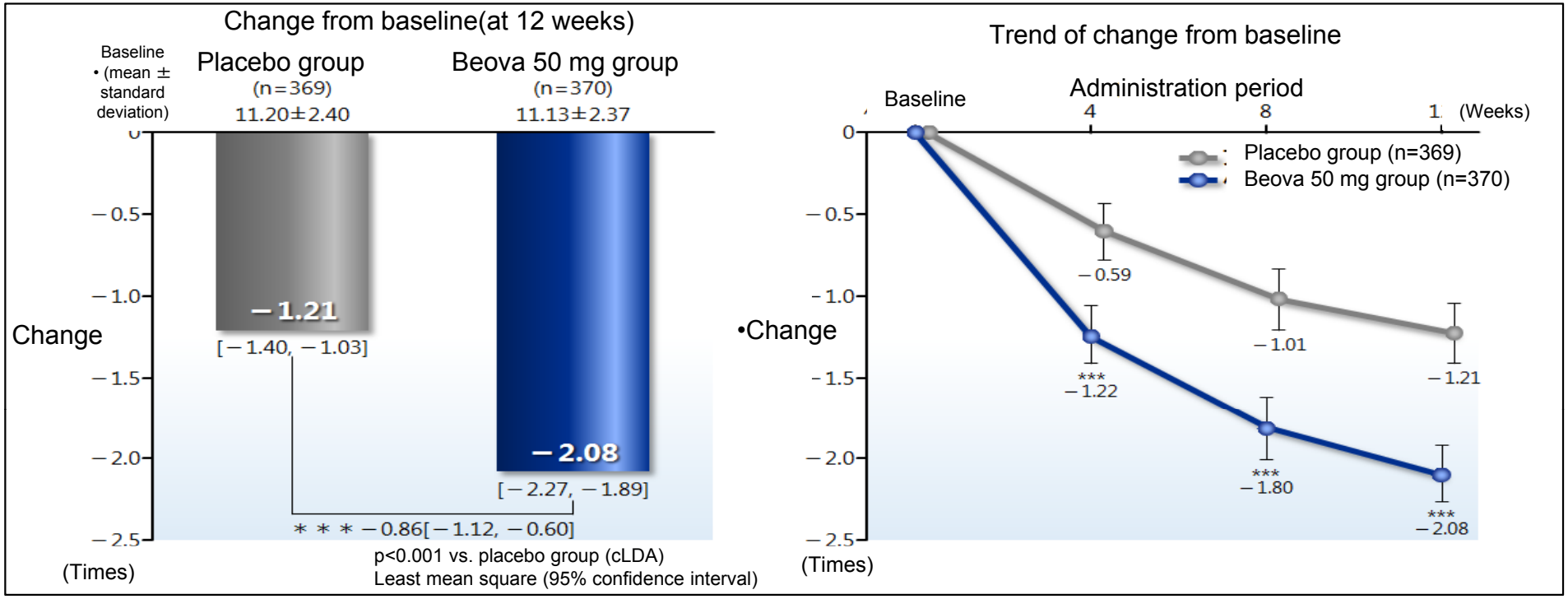
■Generic name: Vibegron

Development status

■Approval obtained: September 21, 2018 ■ To be listed in the NHI drug price list in November

- ◆ Co-developed and co-marketed with Kissei Pharmaceutical Co., Ltd. In Japan
- ◆ Indications: Urinary urgency, urinary frequency and urge urinary incontinence associated with overactive bladder
- ◆ Dosage and Administration: The usual oral dosage for adults is 50mg of Vibegron once daily after meal

■ Phase III clinical study results: [Primary endpoint] Average 24-hour urinary frequency



Data available at time of approval (domestic phase III controlled study)

From week 4 of administration, significant improvement was observed for the primary endpoint in the Beova 50 mg group compared with the placebo group and this effect continued through week 12 of administration.

Beova Tablets 50 mg

(selective β3-adrenergic receptor agonist for the treatment of overactive bladder)

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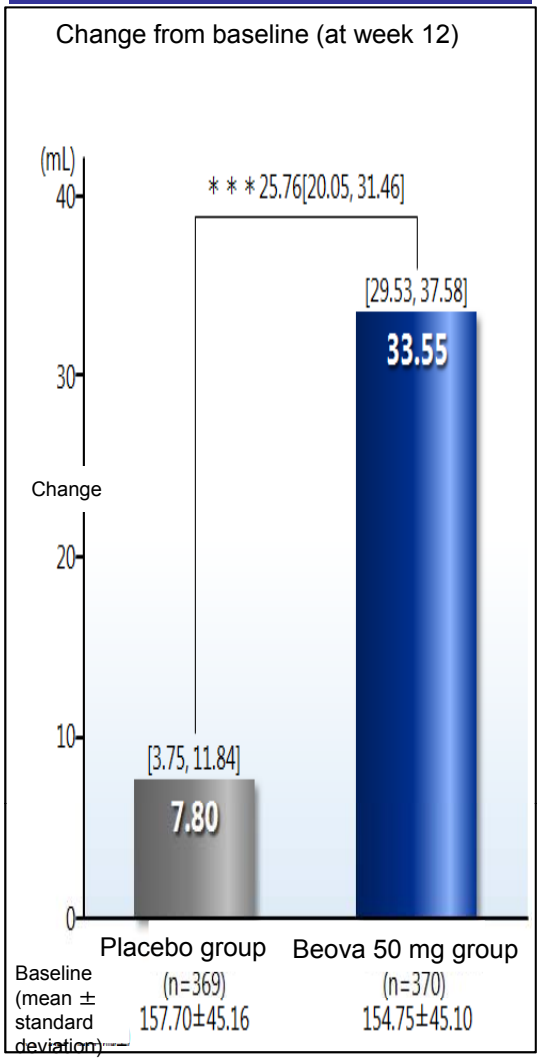
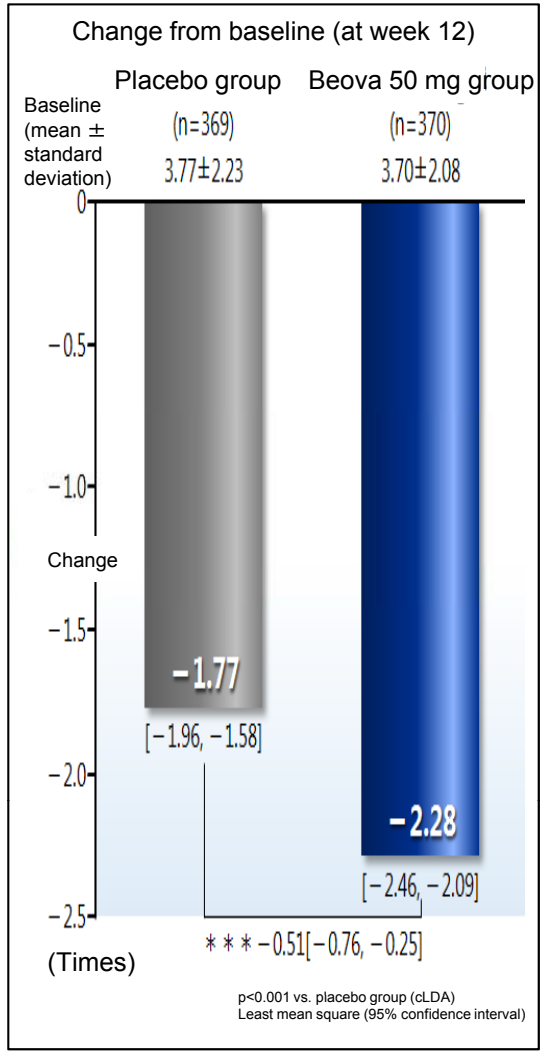
Phase III clinical study results: [Secondary endpoints]

Data available at time of approval (domestic phase III controlled study)

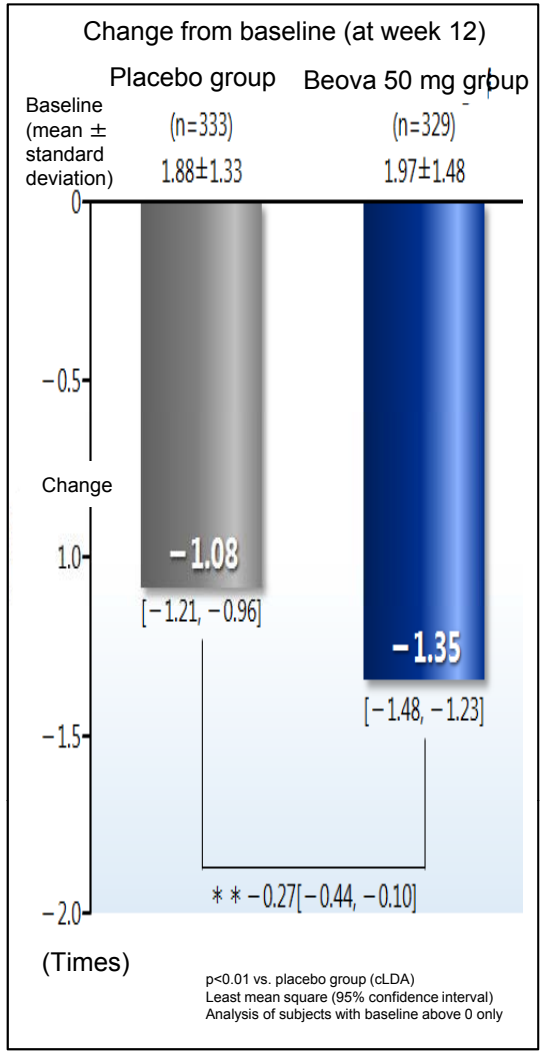
Average voided volume



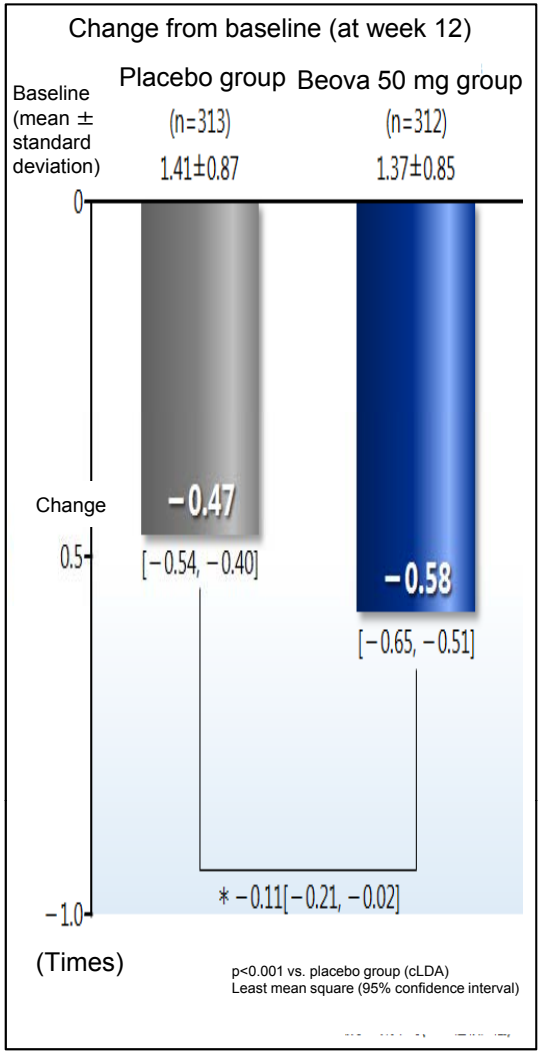
Average number of urgency episodes/24 hour



Average number of incontinence episodes/24 hour



Average frequency of nocturnal urination



Significant improvement was observed for each of the secondary endpoints in the Beova 50 mg group compared with the placebo group (at week 12 of administration).

Expansion of Market Share for Treatments of Overactive Bladder (OAB)

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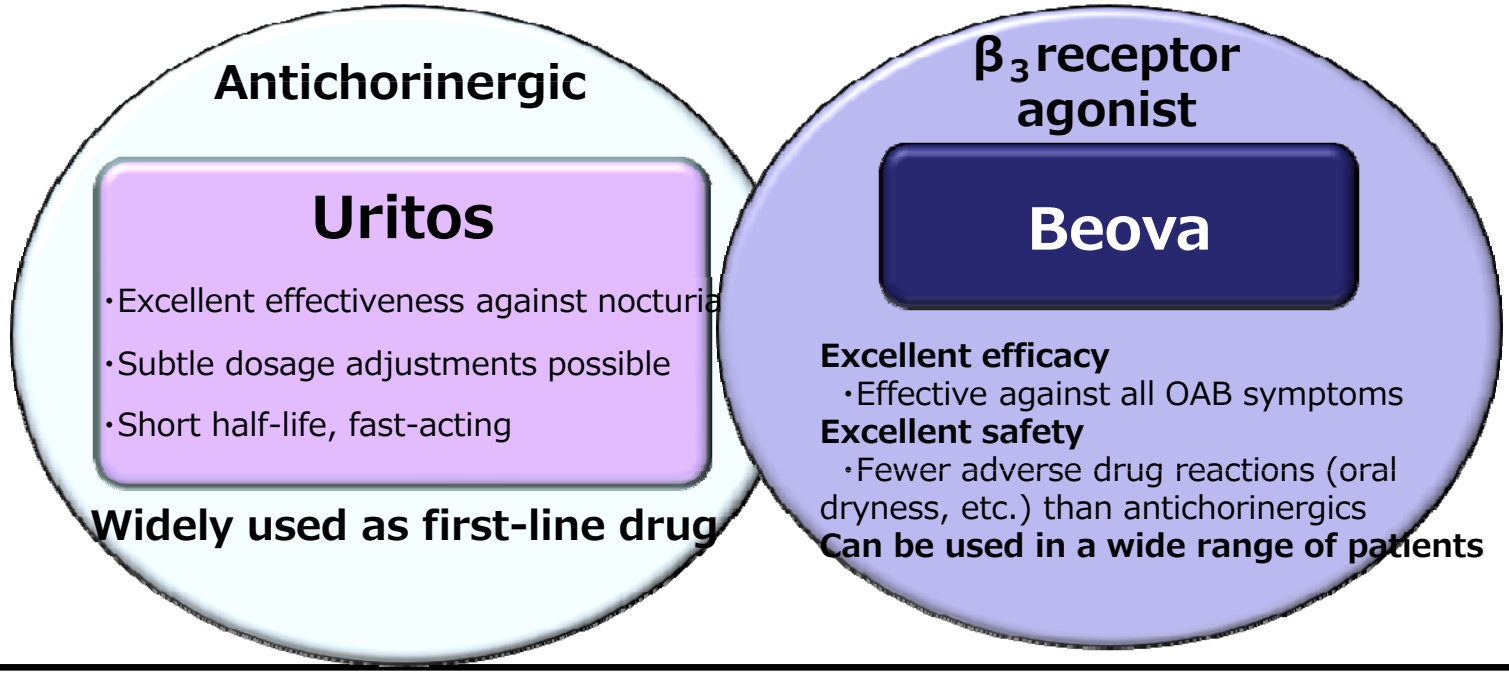
Market for Treatments of Overactive Bladder (OAB)



Background to Beova development

- Developed as new treatment for OAB partly because treatment with anticholinergics is sometimes stopped for reasons such as the onset of adverse drug reactions such as oral dryness or ineffectiveness
- When using β_3 receptor agonists, attention needs to be paid to their effects on the cardiovascular system, such as increased heartrate and changes in blood pressure, and to drug interactions

We aimed to develop a treatment for OAB which is easy to use and has less effect on the cardiovascular system and fewer drug interactions.

We aim to achieve rapid market penetration of Beova and to expand OAB market share by offering both Uritos and Beova.

KRP-N118, Therapeutic Agent for Nocturia

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Development Status

●**Phase II clinical study　(initiated in August 2018)**

Study: Randomized, double-blind, placebo-controlled study

Name of disease:　Nocturia due to nocturnal polyuria

[Primary endpoint] Nocturnal urinary frequency

Overview of KRP-N118

■Mechanism of action

Vasopressin V2 receptor agonist which promotes the reabsorption of water in the renal collecting ducts to reduce urinary output (antidiuresis)

■Features

Excellent absorbability, quickly exerts an antidiuretic effect after administration, and will be promptly eliminated form the body; expected to be a novel **drug for treatment of nocturia due to nocturnal polyuria** with excellent efficacy and safety

*Signed a License Agreement on joint development with Sanwa Kagaku Kenkyusho Co., Ltd. (March 2018)

Basic Policy and initiatives related to capital policy

Shareholder Returns

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Basic Policy(After the change)

・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 (forecast)
Dividend per share (Yen)	¥58 (interim ¥20)	¥58 (interim ¥20)	¥75 (interim ¥30)

Acquisition of Treasury Stock

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Completion of Acquisition of Treasury Stock through Off-Floor Trading for Purchase of Treasury Stock (ToSTNeT-3)

Reason for acquisition of treasury stock

◆To improve the capital efficiency and implement a flexible and agile capital policy in accordance with changes in the business environment.

Terms and conditions for acquisition

◆Class of shares acquired: common shares of the Company
◆ Total number of shares acquired: 16,574,000 shares
◆ Acquisition price: 40,838,336,000 yen (2,464 yen per share)
◆ Delivery date：October 2,2018　※Acquisition date: September 27, 2018

Change to one of the major shareholders, which is the largest shareholder

largest shareholder ： Teijin Limited

Number of voting rights held by the relevant shareholder (number of shares owned) before the change and the ratio to the number of voting rights of all shareholders

	Number of voting rights (Number of shares owned)	Ratio to the number of voting rights of all shareholders*	Ranking among large shareholders
Before the change (as of August 31, 2018)	143,280 rights (14,328,000 shares)	19.20%	1st
After the change	–	–	–

*Number of shares deducted from the total number of shares issued as shares without voting rights: 309,128 shares
Total number of shares issued as of August 31, 2018: 74,947,628 shares

Borrowing of Funds Associated with the Acquisition of Treasury Stock and Future Policy

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■ **Funds for the acquisition of treasury stock**

・**Short-term loan** Around 40.0 billion yen

■ **Future policy**

・Repayment (sales of bond, etc.) by funds on hand

・Around 20.0 billion yen is still to be borrowed

We will seek to maintain a sound financial base with an awareness of credit risks and the cost of capital

Notice Regarding the Cancellation of Treasury Stock

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The Board of Directors of KYORIN Holdings, Inc., (" KYORIN ") at its meeting held today, resolved that KYORIN will cancel a portion of its treasury stock pursuant to Article 178 of the Companies Act of Japan, as stated below.

■Type of shares to be cancelled: Shares of common stock

■Number of shares to be cancelled: 10,339,692 shares
(13.8% of the total issued shares before cancellation)

■Date of Cancellation: November 30, 2018

(For reference)

（1） Status of the stock of the Company as of October 31, 2018 Number of shares issued and outstanding 74,947,628 shares Number of shares of treasury stock 16,800,486 shares

（2） Status of the stock of the Company after the cancellation of treasury stocks Number of shares issued and outstanding 64,607,936 shares Number of shares of treasury stock 6,460,794 shares (10.0% of the total issued shares before cancellation)