## First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2019

- 1. Overview of consolidated results
- 2. Highlights of Business Performance
- 3. Main Product Sales Update
- 4. Changes in Capital Policy and Shareholder Return Policy
- **5.** Financial summary
- 6. Development pipeline

#### [Reference]

7. Segment information

**July 31, 2018** 

#### **KYORIN Holdings, Inc.**

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.



### Outline of First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2019



Units: millions of yen	First quarter Jun / 2015	First quarter Jun / 2016	First quarter Jun / 2017	First quarter Jun / 2018	YoY change (%)
Net sales	26,567	27,707	26,458	25,131	-5.0%
Operating income	2,173	3,244	2,595	1,178	-54.6%
Ordinary income	2,316	3,485	2,805	1,455	-48.1%
Net income	1,757	2,580	2,393	979	-59.1%

Interim term Sep / 2018 (forecast)	YoY change (%)	Year ending Mar / 2019 (forecast)	YoY change (%)
50,200	-1.1%	114,400	+3.4%
1,900	+31.6%	8,600	-2.5%
2,200	+29.9%	9,200	-1.6%
1,500	+20.9%	6,600	+0.4%

#### First Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2019

[Net sales] While sales of our main products Flutiform and Desalex grew, sales of new drugs in Japan remained lower than the year-ago level because of the effect of the drug price system reforms. Meanwhile, sales of generic drugs increased, but overall sales in the Ethical Drugs Business declined. As a result, overall net sales stood at 25,131 million yen (down 5.0% year on year).

[Profit] Gross profit declined 1,545 million yen year on year due to the fall in sales of new drugs in Japan and a rise in the cost of sales ratio following the drug price system reforms. SG&A expenses decreased 129 million yen from a year ago (of which R&D expenses declined 33 million yen) thanks to our efforts to reduce costs, but operating income was 1,178 million yen (down 54.6% year on year), and profit attributable to owners of parent was 979 million yen (down 59.1% year on year).

#### Consolidated Financial Results for the Fiscal Year Ending March 31, 2019(forecast)

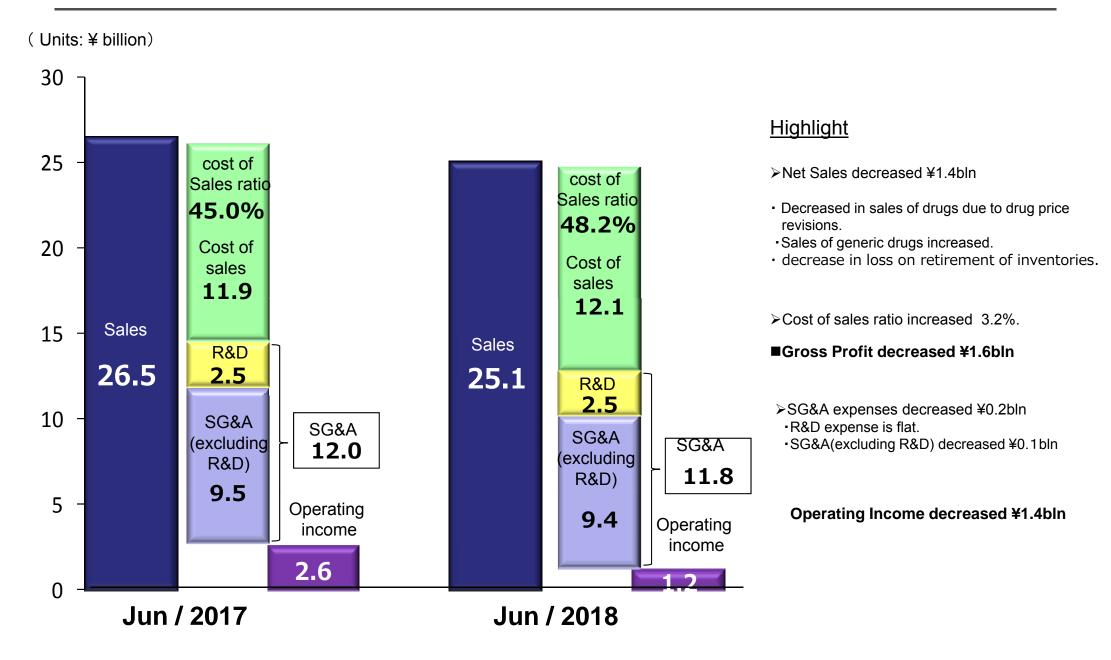
**Dividends (forecast)** 

The results forecasts for the first half and the full year announced on May 10, 2018 remain unchanged as of this moment. (Progress compared with the forecast for the first half: net sales: 50.1%; operating income: 62.0%)

We revised the dividend forecast for the fiscal year ended March 2007, which was announced on May 10, 18, to July 31, 18. Original forecast  $\frac{1}{2}$ 58/ share ( $\frac{1}{2}$ 38 at the end of the term)  $\Rightarrow$  revised forecast  $\frac{1}{2}$ 75/ share ( $\frac{1}{2}$ 45 at the end of the term)

#### **Highlights of Business Performance**





#### **Consolidated Financial Results** for the first Quarter ending March 31, 2019



(¥ billion)	Jun/2017	Jun/2018	Change
Net Sales	26.5	25.1	-1.4
Ethical drugs Business	25.1	23.7	-1.4
◆Sales of new ethical drugs  ●Japan	18.2 18.0	16.2 16.1	-2.0 -1.9
● Overseas	0.2	0.1	-0.1
<b>♦</b> Generic drugs	6.9	7.5	+0.6
Healthcare Business	1.3	1.4	+0.1
Operating Income	2.6	1.2	-1.4
Ordinary Income	2.8	1.5	-1.3
Net Income	2.4	1.0	-1.4

				Year on Year			
■ Net Sales	¥ 25.1l	oin		(-1.4)			
♦ Ethical drugs business	¥ 23.7	bin		(-1.4)			
Sales of new ethical drugs	ugs¥ 16.1	bin		(-1.9)			
	17.6 (1Q)	_	18.6 (1Q)	<u>)                                    </u>			
• Flutiform	2.8 1.9	$\Rightarrow$ $\Rightarrow$	3.0 1.7	(+0.2) (-0.2)			
<ul><li>Uritos</li><li>Desalex</li></ul>	0.5	$\Rightarrow$	1.7	(-0.2) $(+1.0)$			
- Kipres	5.2	$\Rightarrow$	3.3	(-1.9)			
• Pentasa	4.0	$\Rightarrow$	3.5	(-0.5)			
<ul> <li>Mucodyne</li> </ul>	2.1	⇒ 	1.7	(-0.4)			
Sales of new ethical d		ch(11/2016) Prseas	^ 4 la!sa	(-0.1)			
	_	т.	0.1bin	,			
<ul><li>Sales of Generic drugs</li></ul>	5	¥7	7.5bin	( +0.6)			
<ul> <li>Increase of MONTELKAST</li> </ul>	AG sales	Contract ma	anufacturing's	sales decreased			
<b>♦</b> Healthcare Business	¥1.	4bin		( +0.1)			
■ Operating Income	¥1.	2bin		(-1.4)			
Operating Income margin decreased 5.1 percentage points to 4.7%							
Cost of Sales Ratio : increas	sed 3.2 per	centage po	ints (45.0%	5⇒48.2%)			

- - Drug price revision Sales of generic drugs increased
  - ●R&D Ratio: increased 0.4 percentage points (9.4%⇒9.8%) flat ·¥2.5bln⇒¥2.5bln
  - ●SG&A Ratio (excluding R&D expenses): increased 1.5 percentage points •¥9.5bln⇒¥9.4bln ¥-0.1bln
  - Decrease of labor costs.

■ Net Income ¥1.0bin (-1.4)

(35.8%⇒37.3%)

#### **Main Product Sales Update**



( Units: ¥ billion )

		Interir	n term	Full term		
	Product name	Sep/2017	Sep/2018 (forecast)	Mar/2018	Mar/2019 (forecast)	
	Flutiform (Combination drug for asthma treatment)	5.4	5.7	11.9	12.3	
	Uritos (Kyorin) (Overactive bladder)	3.6	3.4	7.2	6.8	
Sales of	Desalex (Antiallergic Agent)	0.9	3.0	4.9	8.1	
new ethical drugs	Kipres (LT receptor antagonist)	3.9	2.9	8.3	6.0	
(Japan)	For children	5.1	2.9	10.5	7.2	
	Pentasa (Ulcerative colitis and Crohn's diseasetreatment)	8.0	7.3	15.3	14.5	
	Mucodyne (Mucoregulant)	3.9	3.2	8.7	7.2	
Generic drugs	MONTELUKAST Tablets "KM"	5.0	4.8	11.7	9.8	
Over-the- counter drugs	Milton (Disinfectant)	1.1	1.1	2.2	2.3	

First quarter (April 1 to June 30)									
Jun/2017	Jun/2018	YoY change (%)	Progress to Interim term forecast(%)	Progress to Full term forecast(%)					
2.8	3.0	+9.4%	52.5%	24.4%					
1.9	1.7	-8.8%	50.1%	24.7%					
0.5	1.5	+230.8%	48.6%	18.4%					
2.0	1.6	-23.1%	53.7%	25.9%					
3.1	1.7	-45.7%	57.6%	23.5%					
4.0	3.5	-12.4%	47.2%	24.0%					
2.1	1.7	-22.5%	51.4%	22.8%					
2.7	3.3	+21.9%	68.1%	33.6%					
0.5	0.6	+3.7%	47.6%	24.3%					
				4					



# **Changes in Capital Policy and Shareholder Return Policy**

#### **Changes in Capital Policy**



#### Before the change

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

As for the return to shareholders, we aim for "stable dividends" on a basis of the present dividend standard.

#### Reason of the Changes in Capital Policy

- ♦ Considering the perspective of the recovery of the corporate earnings caused by the implementation of our key strategies.
- Taking into consideration the current capital market conditions and the financial situation of the Company, we decided to change the policy from capital accumulation to capital efficiency improvement
- ♦ We aim to continue this new shareholder return policy unless there is a special change in the business environment.

#### Changes in Capital Policy and Shareholder Return Policy

#### Basic idea

- Please note that there is no change in our business strategy towards the realization of the medium-term business plan "HOPE100-Stage 2-", and we will continue to make our best efforts to achieve our target figures in that business plan by investing for continuous growth.
- We aim to further improve the shareholder's value and increase efficiency of capital to strengthen the return to shareholdersby strengthening shareholder return taking DOE (shareholders' equity dividend rate) into account

#### **Shareholder Returns**



#### **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.

#### **Dividends**

	FY2017	FY2018 (orginal forecast)	FY2018 (revise forecast)
Dividend per share (Yen)	¥58 (Year-end ¥38)	<b>¥58</b> (Year-end ¥38)	<b>¥75</b> (Year-end ¥45)
Consolidated payout ratio(%)	65.9%	65.7%	84.9%

<sup>\*</sup> We revised the dividend forecast for the fiscal year ended March 2007, which was announced on May 10, 18, to July 31, 18.



### Financial summary

## **Consolidated Financial Results for the first Quarter ending March 31, 2019**



	Interin	n term	Full	term		First quarter (April 1 to June 30)				
(Units: ¥million)	Sep/2017	Sep/2018 (forecast)	Mar/2018	Mar/2017 (forecast)	Jun/2017	Jun/2018	Change	YoY change (%)	Progress to interim term forecast (%)	Progress to full term forecast (%)
Sales	50,758	50,200	110,640	114,400	26,458	25,131	-1,327	-5.0%	50.1%	22.0%
Ethical drugs business	47,977	47,400	104,703	108,400	25,112	23,735	-1,377	-5.5%	50.1%	21.9%
◆Sales of new ethical drugs	34,972	34,100	77,041	80,900	18,242	16,204	-2,038	-11.2%	47.5%	20.0%
●Japan	34,449	33,600	73,702	79,900	17,999	16,057	-1,942	-10.8%	47.8%	20.1%
●Overseas	523	500	3,339	1,000	242	146	-96	-39.7%	29.2%	14.6%
◆Generic drugs	13,005	13,200	27,662	27,400	6,870	7,531	+661	+9.6%	57.1%	27.5%
Healthcare business	2,781	2,800	5,937	6,000	1,346	1,396	+50	+3.7%	49.9%	23.3%
Operating income	1,443	1,900	8,822	8,600	2,595	1,178	-1,417	-54.6%	62.0%	13.7%
Ordinary income	1,693	2,200	9,345	9,200	2,805	1,455	-1,350	-48.1%	66.1%	15.8%
Net income	1,240	1,500	6,574	6,600	2,393	979	-1,414	-59.1%	65.3%	14.8%

#### Main R&D Activities -1 (as of July 31 2018)



#### Ph III ~ Application submitted

Sta	ge	Compound/	Therapy area	Outsin	Fashina	Occurrents
Japan	Overseas	Code	/Action	Origin	Features	Comments
Application (9/2017)	PhⅢ: UROVANT	KRP-114V	Overactive bladder	Merck & Co.,	-Expectation of high compliance in taking medicine with less side effects than the conventional drugs for overactive bladder Less drug interaction as β3 receptor agonist - β3 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) *License agreement with Merck & Co., Inc., for Asia (4/2017)
Application (4/2017)		KRP- AM1977X (Oral agent)	New quinolone synthetic antibacterial agent	In-house	-Superior ability to combat drug-resistant gram- positive bacteria (incl. MRSA) -has a powerful antimicrobial activity against anaerobic bacteria - Expectation of high clinical effects with excellent	
PhⅢ (3/2016)		KRP- AM1977Y (Injection)	New quinolone synthetic antibacterial agent	In-house	tissue penetration -High degree of safety expected since safety hurdles cleared prior to clinical trials	
PhⅢ (3/2017)		KRP-116D	Interstitial cystitis	_	Evaluation committee on unapproved or off-labeled drugs with high medical needs "Dimethyl sulfoxide(DMSO)"	
PhⅢ (6/2017)		KRP-108P	Anti-asthmatic	(U.K.) Vectura	Expand the indication of Flutiform to pediatric patients	

#### Main R&D Activities -2 (as of July 31 2018)



#### POC Project (Ph I ~ Ph II)

\*Changes from the previous announcement (May 10 2018)

St	Stage		Stage Compou		Therapy area	Origin	Footures	Commente
Japan	Overseas	Code	/Action	Origin	Features	Comments		
PhⅡ		KRP-N118 (SK-1404)	Nocturia Due to Nocturnal Polyuria	SANWA KAGAKU KENKYUSH O CO., LTD.	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). With its high efficacy and safety, the drug is expected to be a therapeutic agent for nocturia due to nocturnal polyuria.	•License agreement with SANWA KAGAKU KENKYUSHO CO., LTD, (3/2018)		
<b>※Ph II</b> (6/2018)		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)  [US] Momotaro-Gene prostate cancer(Ph I / II )  [JP] Okayama University liver cancer(Ph I / I b)		

#### Licensing development

Stage/ Overseas	Compound/ Code	Licensee / Collaborative research	Therapy area/Action	Origin	Features	Comments
Ph I	FPR-2 agonist program	BMS	Non- disclosure	In-house	FPR-2 agonists that mainly inhibit the migration of neutrophils and exhibit anti-inflammatory action.	License agreement with BMS (12/2015)



### Reference

## **Segment information for the first Quarter Ending March 31, 2019**



#### Sales, Profit or Loss of each report segment

(Units:¥ billion)	Sales	Year on Year	Profit	Year on Year
total	25.1	-1.4	1.2	-1.4
Ethical drugs business	23.7	-1.4	1.1	-1.4
♦Sales of new ethical drugs	16.2	-2.0		
●Japan	16.1	-1.9		
● Overseas	0.1	-0.1		
<b>♦</b> Generic drugs	7.5	+0.6		
Healthcare business	1.4	+0.1	0	0
Amount of adjustment	_	_	0.1	0