

Third Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2020

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February 5, 2020

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.



Overview of Third Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2020

(¥ million)	Dec/2016	Dec/2017	Dec/2018	Dec/2019	Y to Y change (%)	Mar/2020 (forecast)	Y to Y change (%)
Net Sales	86,836	82,923	82,017	78,614	- 4.1	109,400	- 3.7
Operating Income	7,313	7,805	6,794	5,271	- 22.4	6,500	- 27.6
Ordinary Income	7,716	8,246	7,124	5,836	- 18.1	7,100	- 24.8
Net Income	4,723	6,119	5,112	4,374	- 14.4	5,400	- 21.4

Third Quarter Consolidated Financial Results for the Fiscal Year Ending March 31, 2020

[Net Sales] In new ethical drugs (Japan), results remained lower than a year ago due to effects from the suspended supply of Desalex and NHI drug price revisions, despite the growth of the mainstay product Flutiform and Beova. Meanwhile, sales increased in generic drugs due to the sales of Mometasone Nasal (authorized generic [AG]), and sales increased in new ethical drugs (Overseas). As a result net sales decreased 3,402 million yen (down 4.1%) from year on year, to 78,614 million yen.

[Profit] Gross profit declined 1,737 million yen year on year due to a fall in net sales and effect of revision of NHI drug price. Selling, general and administrative expenses decreased 215 million yen year on year (of which research and development expenses decreased 150 million yen). Operating income was 5,271 million, down 1,522 million yen (down 22.4%) from year on year and Profit attributable to owners of parent was 4,374 million yen (down 14.4% year on year).

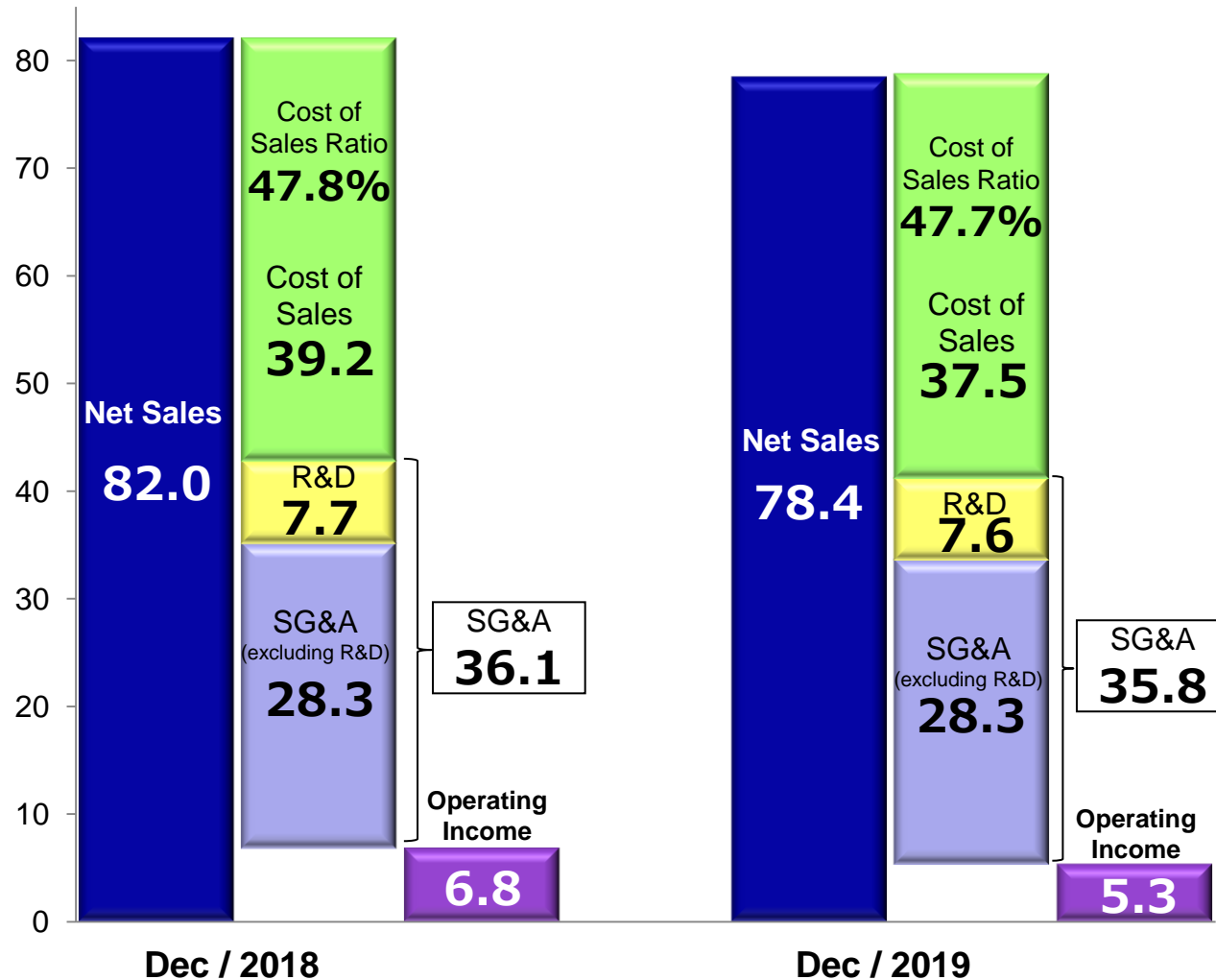
Consolidated Financial Results for the Fiscal Year Ending March 31, 2020 (forecast)

The results forecasts for the full year announced on November 7, 2019 remain unchanged.
 (Progress compared with the forecast for the fiscal year ending March 31, 2020: net sales: 71.9%; operating income: 81.1%)

There is no change to the dividend forecast announced on May 13, 2019 (annual dividend of 75 yen per share).

Highlights of Business Performance

(Units: ¥ billion)



➢ Net Sales decreased ¥3.4billion year on year
 ・Decrease of sales of new drugs in Japan
 (Effects from the suspended supply of Desalex)

➢ Cost of sales ratio decreased 0.1%
 ・Increase by NHI drug price revisions
 ・Decrease by product mix

■ Gross Profit decreased ¥1.7billion year on year

➢ SG&A expenses decreased ¥0.3billion year on year
 ・R & D expenses decreased ¥0.1billion
 ・SG&A(excluding R&D) remained flat

■ Operating Income decreased
 ¥1.5billion year on year

Consolidated Financial Results for the Third Quarter ending March 31, 2020

(unit : ¥ billion)

(Year on Year)

	Dec/2018	Dec/2019	Change
Net Sales (total)	82.0	78.6	- 3.4
Ethical drugs Business	77.6	74.2	- 3.4
◆Sales of new ethical drugs	56.2	52.2	- 4.0
●Japan	55.5	51.0	- 4.5
●Overseas	0.6	1.2	+ 0.6
◆Generic drugs	21.4	22.0	+ 0.6
Healthcare Business	4.4	4.4	0
Operating Income	6.8	5.3	- 1.5
Ordinary Income	7.1	5.8	- 1.3
Net Income	5.1	4.4	- 0.7

■ Net Sales	¥78.6bln	(- 3.4)
◆ Ethical drugs business	¥74.2bln	(- 3.4)
● Sales of new ethical drugs in Japan	¥51.0bln	(- 4.5)
19.3 (3Q)	20.3 (3Q)	
• Flutiform	9.8 ⇒ 10.8	(+ 1.0)
• Desalex	4.8 ⇒ 0.8	(- 4.0)
• Kipres	10.0 ⇒ 8.6	(- 1.4)
• Nasonex	4.1 ⇒ 3.8	(- 0.3)
• Uritos	5.1 ⇒ 4.6	(- 0.5)
• Beova	0.7 ⇒ 2.2	(+ 1.5)
• Pentasa	10.5 ⇒ 10.3	(- 0.2)
• Mucodyne	5.1 ⇒ 4.5	(- 0.6)
● Sales of new ethical drugs in Overseas	¥1.2bln	(+ 0.6)
Increased the sales of Gatifloxacin		
● Sales of Generic drugs	¥22.0bln	(+ 0.6)
The contribution to sales made by Mometasone Nasal (AG)		
◆ Healthcare Business	¥4.4bln	(0)
■ Operating Income	¥5.3bln	(- 1.5)
◆ Operating Income margin decreased 1.6 percentage points to 6.7%		
● Cost of Sales Ratio : 47.8% ⇒ 47.7% decreased 0.1 percentage points		
[Increase] NHI drug price revisions, etc.		
[Decrease] Product mix (Increase of Sales of Beova and Flutiform) , etc.		
● R&D Ratio : 9.4% ⇒ 9.6% increased 0.2 percentage points		
* ¥7.7bln ⇒ ¥7.6bln (¥ - 0.1bln)		
● SG&A Ratio (excluding R&D) : 34.5% ⇒ 35.9% (+ 1.4%)		
* ¥28.3bln ⇒ ¥28.3bln (¥ 0bln)		
■ Net Income	¥4.4bln	(- 0.7)

Main Product Sales Update

(Units: ¥billion)		Sep/ 2018	Sep/ 2019	Dec/ 2018	Dec/ 2019	Change	Change(%)	Mar/2019	Mar/2020 (forecast)
Sales of new ethical drugs (Japan)	Flutiform (Combination drug for asthma treatment)	6.1	6.7	9.8	10.8	+1.0	+10.0	13.1	14.1
	Desalex (Antiallergic Agent)	2.8	0	4.8	0.8	-4.0	-83.2	3.7	5.0
	Kipres for adult (Leukotriene Receptor Antagonist)	2.9	2.4	4.4	3.8	-0.6	-14.7	6.2	4.7
	for children	3.3	3.0	5.5	4.8	-0.7	-13.0	7.6	6.3
	Nasonex (Spray type allergic rhinitis remedy)	1.3	2.7	4.1	3.8	-0.3	-7.4	12.8	6.2
	Uritos (Kyorin) (Therapeutic agent for overactive bladder)	3.5	3.0	5.1	4.6	-0.5	-9.6	6.6	5.9
	Beova (Kyorin) (β3 adrenergic receptor agonist overactive bladder therapeutics)	—	0.6	0.7	2.2	+1.5	+203.0	0.7	2.8
	Pentasa (Ulcerative colitis and Crohn's disease treatment)	7.1	6.8	10.5	10.3	-0.2	-1.8	13.5	12.7
Mucodyne (Mucoregulant)	3.1	2.8	5.1	4.5	-0.6	-11.8	6.8	6.1	
Generic Drugs	Montelukast Tablets "KM" (LT receptor antagonist)	5.3	5.4	8.3	8.3	0	-0.5	11.9	11.5
	Mometasone Nasal 50mg "KYORIN" (Spray type allergic rhinitis remedy)	—	0.4	—	1.1	+1.1	—	—	1.8
Over-the- counter drugs	Milton (Disinfectant)	1.1	1.1	1.7	1.7	0	-3.6	2.2	2.2

Development pipeline

Development pipeline

Main R&D Activities -1 (as of February 5 2020)

Ph III ~ Application submitted

※Changes from the previous announcement (Nov 7 2019)

Stage		Compound/ Code	Therapy area /Action	Origin	Features	Comments
Japan	Overseas					
Application (10/2019)		KRP-AM1977Y (Injection)	New quinolone synthetic antibacterial agent	In-house	A novel quinolone injection developed specifically for the treatment of lower respiratory tract infections 1. Highly distributed in the lung, showing strong antibacterial activity against pathogenic bacteria of respiratory tract infection 2. Effective against both aerobic and anaerobic bacteria, and able to administer once a day 3. Showed effectiveness against aspiration pneumonia, pulmonary suppuration, and lung abscess	
Preparing for Application		KRP-116D	Interstitial cystitis	—	Evaluation committee on unapproved or off-labeled drugs with high medical needs “Dimethyl sulfoxide(DMSO)”	
Application (7/2019)		KRP-108P	Anti-asthmatic	(U.K.) Vectura	Expand the indication of Flutiform to pediatric patients	

•MK-7264, a drug for chronic coughing: MSD is working on Phase III development.
 Concluded a memorandum of understanding for sales collaboration.

※ Oral new quinolone synthetic antibacterial agent “Lasvic tablets 75mg”: released in January 2020.

Development pipeline

Main R&D Activities -2 (as of February 5 2020)

POC Project (Ph I ~ Ph II)

※Changes from the previous announcement (Nov 7 2019)

Stage		Compound/ Code	Therapy area /Action	Origin	Features	Comments
Japan	Overseas					
Ph II (6/2018)		Ad-SGE-REIC	malignant pleural mesothelioma	Okayama University	<p>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.</p> <p>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.</p>	<p>Adopted to Next generation Technology Transfer Program (NexTEP) (6/2014)</p> <p>[US] Momotaro-Gene prostate cancer(Ph I / II)</p> <p>[JP] Okayama University liver cancer(Ph I / I b)</p>

※ It was decided to discontinue development of "KRP-N118", for it was estimated difficult for realization of pre-configured product profiles.

Status of Introduced Program

※[ATYR1923] : Code of aTyr Pharma, Inc

- Entered into collaboration and license agreement with aTyr Pharma, Inc (1/2020)
- Ph 1b/2a Clinical Trial is in progress in the United States by aTyr Pharma, Inc
- It is a fusion protein drug having the action to suppress, by binding to neuropilin-2 (NRP2) receptor, the excessive activation of immune cells, and is a potential first-in-class therapy to treat inflammatory diseases such as pulmonary sarcoidosis.

Status of Licensed Compound / Program

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)
Ph I	KRP-203	Implementing licensing activities	GvHD		Sphingosine-1-Phosphate Receptor Agonist	Because Novartis (licensee) decided to discontinue development of KRP-203 for strategic reasons, Kyorin receive the return of development rights.

Segment information for the Third Quarter Ending March 31, 2020

Sales, Profit or Loss of each report segment

(unit : ¥billion)	Sales	change Y/Y	Profit	change Y/Y
Net Sales (total)	78.6	- 3.4	5.3	- 1.5
Ethical drugs business	74.2	- 3.4	4.7	- 1.6
◆Sales of new ethical drugs	52.2	- 4.0		
○Japan	51.0	- 4.5		
○Overseas	1.2	+ 0.6		
◆Generic drugs	22.0	+ 0.6		
Healthcare business	4.4	0	0.5	+ 0.3
Amount of adjustment	-	-	0.1	- 0.2

Consolidated Financial Results for the Third Quarter ending March 31, 2020

(unit : ¥million)	Sep/2018	Sep/2019
Sales	50,360	48,299
Ethical drugs business	47,581	45,505
◆Sales of new ethical drugs	34,028	31,339
●Japan	33,424	30,949
●Overseas	604	390
◆Generic drugs	13,552	14,166
healthcare business	2,779	2,793
Operating Income	2,852	783
Ordinary Income	3,183	1,076
Net Income	2,217	834

Dec/2018	Dec/2019	Change	% Y/Y
82,017	78,614	-3,402	-4.1
77,601	74,223	-3,377	-4.4
56,165	52,185	-3,980	-7.1
55,535	50,960	-4,575	-8.2
629	1,224	+595	+94.5
21,436	22,038	+602	+2.8
4,415	4,390	-25	-0.6
6,794	5,271	-1,522	-22.4
7,124	5,836	-1,287	-18.1
5,112	4,374	-738	-14.4

Mar/2019	Mar/2020 (forecast)
113,620	109,400
107,859	103,400
78,525	72,400
77,694	71,000
830	1,400
29,334	31,000
5,761	5,900
8,972	6,500
9,438	7,100
6,869	5,400