

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

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February 5, 2019

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

| (¥ million) | Dec/2015 | Dec/2016 | Dec/2017 | Dec/2018 | YoY change (%) | Mar/2019 (revised forecast) | YoY change (%) | Mar/2019 (original forecast) |
|------------------|----------|----------|----------|---------------|----------------|--------------------------------|----------------|---------------------------------|
| Net Sales | 89,469 | 86,836 | 82,923 | 82,017 | - 1.1 | 110,600 | - 0.0 | 114,400 |
| Operating Income | 14,666 | 7,313 | 7,805 | 6,794 | - 13.0 | 8,200 | - 7.1 | 8,600 |
| Ordinary Income | 14,946 | 7,716 | 8,246 | 7,124 | - 13.6 | 8,600 | - 8.0 | 9,200 |
| Net Income | 10,831 | 4,723 | 6,119 | 5,112 | - 16.5 | 6,100 | - 7.2 | 6,600 |

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

【Net Sales】 Sales of new drugs (in Japan) were higher than the year-ago level because revenues from our main product Flutiform grew steadily and sales of the new overactive bladder drug Beova also contributed to growth. Revenues from generic medicine also increased. However, sales of new drugs (overseas) decreased mainly due to the absence of a lump-sum payment for progress in the development of a license-out product recorded the previous fiscal year, and overall net sales fell 906 million yen (or 1.1%) year on year, to 82,017 million yen.

【Profit】 Gross profit fell 3,648 million yen year on year, reflecting a higher cost of sales ratio as a result of National Health Insurance (NHI) price revision and a decrease in lump-sum payments for progress in the development of license-out products recorded the previous fiscal year. Meanwhile, SG&A expenses decreased 2,637 million yen year on year (including a reduction of 2,316 million yen in R&D expenses) thanks to cost-cutting initiatives, and operating income was 6,794 million yen, down 1,011 million yen (or 13.0%) year on year. Profit attributable to owners of parent amounted to 5,112 million yen (down 16.5% from the year-ago level).

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

The Company revised its consolidated financial results forecast for the fiscal year ending March 31, 2019 announced on May 10, 2018

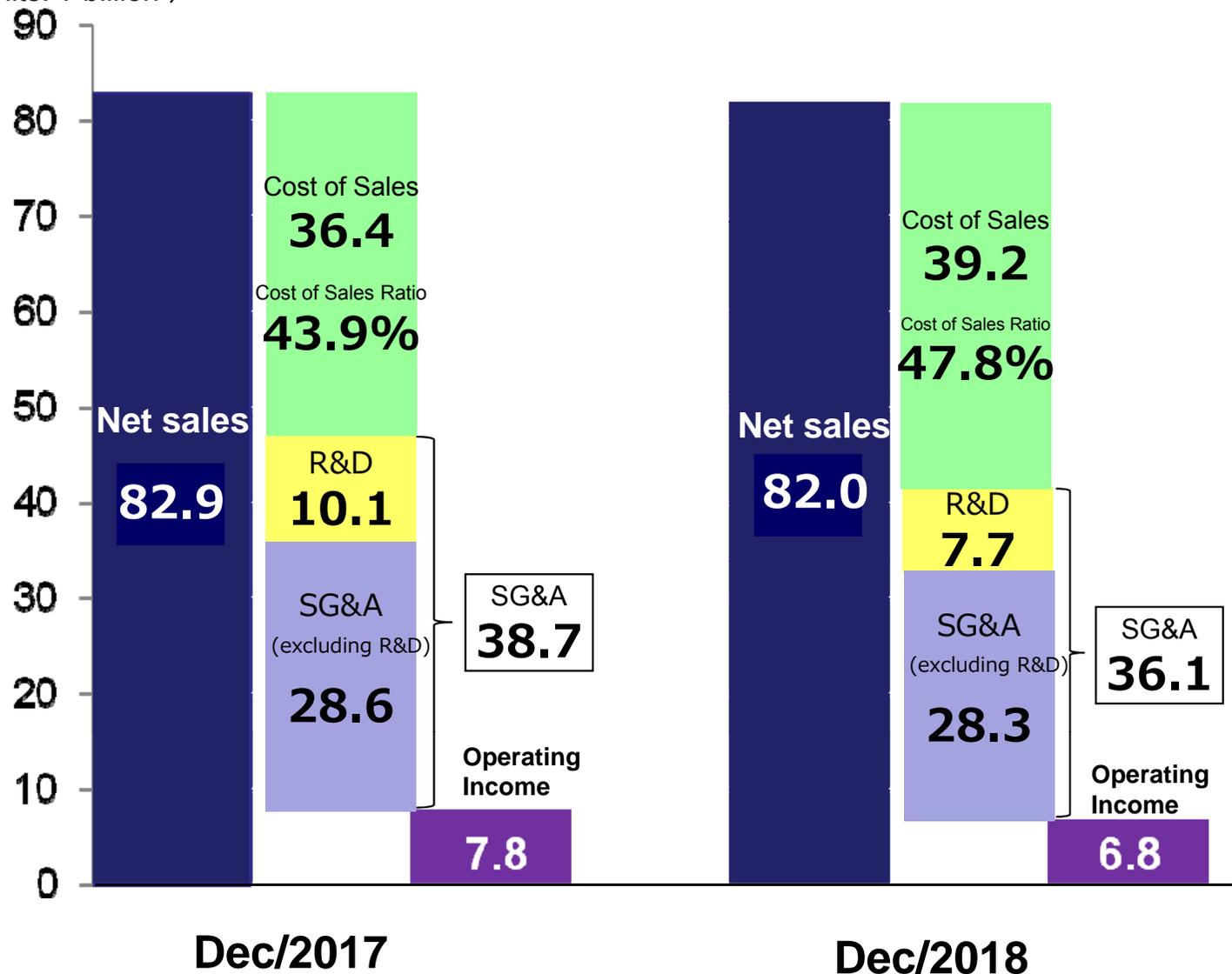
【Net sales】In light of business results for the first nine months of the current fiscal year and the recall of DESALEX, the Company revised its net sales forecast.

【Profit】The Company revised its profit forecast as shown above, as it expects that gross profit will decrease due to the downward revision of sales but that SG&A expenses will be less than initially forecast thanks to cost-cutting initiatives implemented since the beginning of this fiscal year.

【Dividend】There is no change to the dividend forecast (end of second quarter: 30 yen per share; annual dividend: 75 yen per share) announced on July 31, 2018.

Highlights of Business Performance

(Units: ¥ billion)



- **Net Sales decreased ¥0.9billion year on year.**
- **Cost of sales ratio increased 3.9%.**
 - Drug price revisions
 - Decrease in lump-sum revenue due to out-licensed product in the previous year
- **Cost of sales ratio increased 0.2%.**

■ **Gross Profit decreased ¥3.6billion year on year**

➤ **SG&A expenses decreased ¥2.6billion year on year.**

- Efforts to reduce costs
- R & D expenses decreased ¥2.4billion
- SG&A(excluding R&D) decreased ¥0.3billion

■ **Operating Income decreased ¥1.0billion year on year.**

Consolidated Financial Results

for the Third Quarter ending March 31, 2019

(unit : ¥ billion)

Year on Year

| | Dec/2017 | Dec/2018 | Change |
|-----------------------------|----------|----------|--------|
| Net Sales (total) | 82.9 | 82.0 | -0.9 |
| Ethical drugs Business | 78.5 | 77.6 | -0.9 |
| ◆Sales of new ethical drugs | 57.9 | 56.2 | -1.7 |
| ●Japan | 54.8 | 55.5 | +0.7 |
| ●Overseas | 3.1 | 0.6 | -2.5 |
| ◆Generic drugs | 20.6 | 21.4 | +0.8 |
| Healthcare Business | 4.4 | 4.4 | 0 |
| Operating Income | 7.8 | 6.8 | -1.0 |
| Ordinary Income | 8.2 | 7.1 | -1.1 |
| Net Income | 6.1 | 5.1 | -1.0 |

| | | |
|---|-------------|---------|
| ■ Net Sales | ¥82.0bln | (- 0.9) |
| ◆ Ethical drugs business | ¥77.6bln | (- 0.9) |
| ● Sales of new ethical drugs | ¥55.5bln | (+ 0.7) |
| Dec/2017⇒Dec/2018 | | |
| · Flutiform | 8.9 ⇒ 9.8 | (+0.9) |
| · Uritos | 5.6 ⇒ 5.1 | (-0.5) |
| · Desalex | 2.1 ⇒ 4.8 | (+2.7) |
| · Kipres | 14.2 ⇒ 10.0 | (-4.2) |
| · Pentasa | 12.2 ⇒ 10.5 | (-1.7) |
| · Mucodyne | 6.6 ⇒ 5.1 | (-1.5) |
| · Nasonex | — ⇒ 4.1 | (+4.1) |
| · Beova | — ⇒ 0.7 | (+0.7) |
| ● Sales of new ethical drugs in Overseas | ¥0.6bln | (- 2.5) |
| · Decrease in lump-sum revenue due to out-licensed product in the previous year | | |
| ● Sales of Generic drugs | ¥21.4bln | (+ 0.8) |
| · Increase sales of generic drugs released this fiscal year | | |
| ◆ Healthcare Business | ¥4.4bln | (+ 0) |
| ■ Operating Income | ¥6.8bln | (- 1.0) |
| ◆ Operating Income margin decreased 1.1 percentage points to 8.3% | | |
| ● Cost of Sales Ratio : 43.9%⇒47.8% increased 3.9 percentage points | | |
| · Drug price revisions | | |
| · Decrease in lump-sum revenue due to out-licensed product in the previous year | | |
| · Decrease in loss on retirement of inventories | | |
| ● R&D Ratio : 12.1%⇒9.4% decreased 2.7 percentage points | | |
| * ¥10.1bln⇒¥7.7bln (-¥2.4bln) | | |
| · Progress of development project (previous year). | | |
| ● SG&A Ratio : 34.5%⇒34.5% Flat | | |
| * ¥28.6bln⇒¥28.3bln (-¥0.3bln) | | |
| · Decrease of Labor costs, Selling costs. | | |
| ■ Net Income | ¥5.1bln | (- 1.0) |

Revision of Consolidated Business Results Forecasts for Fiscal Year Ending March 31, 2019

(unit : ¥ billion)

| | Mar/2018 | Mar/2019 (original forecast) | Mar/2019 (revised forecast) | Change |
|-----------------------------------|----------|------------------------------------|-----------------------------------|--------|
| Net Sales (total) | 110.6 | 114.4 | 110.6 | - 3.8 |
| Ethical drugs Business | 104.7 | 108.4 | 104.6 | - 3.8 |
| ◆Sales of new ethical drugs | 77.0 | 80.9 | 77.1 | - 3.8 |
| ○Japan | 73.7 | 79.9 | 76.1 | - 3.8 |
| ○Overseas | 3.3 | 1.0 | 1.0 | 0 |
| ◆Generic drugs | 27.7 | 27.4 | 27.4 | 0 |
| Healthcare Business | 5.9 | 6.0 | 6.0 | 0 |
| Operating Income | 8.8 | 8.6 | 8.2 | - 0.4 |
| Ordinary Income | 9.3 | 9.2 | 8.6 | - 0.6 |
| Net Income | 6.6 | 6.6 | 6.1 | - 0.5 |

【Main points of forecast revision】

■ The Company revised its business results forecast in light of business results for the first nine months of the current fiscal year and the voluntary recall of Desalex Tablets 5mg for the treatment of allergic diseases (see the news release dated January 7, 2019 for further details).

【Net sales】

For the reason stated above, in the ethical drugs business, revenues from core products such as PENTASA and DESALEX are now expected to be less than forecast.

【Profits】

The Company revised its profit forecasts as shown in the above table as it expects that gross profit will decrease due to the downward revision of sales but that SG&A expenses will be less than initially forecast thanks to cost-cutting initiatives implemented since the beginning of the current fiscal year,

The Company is currently consulting MSD K.K., which is the holder of marketing approval for DESALAX, regarding action to be taken in response to the voluntary recall and suspension of sales for DESALEX, and will promptly disclose any new information that requires disclosure.

Main Product Sales Update

| (Units: ¥billion) | | Sep/ 2017 | Sep/ 2018 | Dec/2017 | Dec/2018 | Change | (%) Change | Mar/2018 | Mar/2019 (revised forecast) | Mar/2019 (original forecast) |
|---|--|--------------|--------------|----------|-------------|--------|---------------|----------|-----------------------------------|------------------------------------|
| Sales of new ethical drugs (Japan) | Flutiform (Combination drug for asthma treatment) | 5.4 | 6.1 | 8.9 | 9.8 | +0.9 | +9.8 | 11.9 | 12.3 | 12.3 |
| | Uritos (Kyorin) (Overactive bladder) | 3.6 | 3.5 | 5.6 | 5.1 | -0.5 | -8.7 | 7.2 | 6.8 | 6.8 |
| | Desalex (Antiallergic Agent) | 0.9 | 2.8 | 2.1 | 4.8 | +2.7 | +231.5 | 4.9 | 4.8 | 8.1 |
| | Kipres for adult (LT receptor antagonist) | 3.9 | 2.9 | 6.1 | 4.4 | -1.7 | -27.0 | 8.3 | 6.0 | 6.0 |
| | Kipres for children (LT receptor antagonist) | 5.1 | 3.3 | 8.1 | 5.5 | -2.6 | -31.4 | 10.5 | 7.2 | 7.2 |
| | Pentasa (Ulcerative colitis and Crohn's disease treatment) | 8.0 | 7.1 | 12.2 | 10.5 | -1.7 | -13.9 | 15.3 | 13.7 | 14.5 |
| | Mucodyne (Mucoregulant) | 3.9 | 3.1 | 6.6 | 5.1 | -1.5 | -22.0 | 8.7 | 7.2 | 7.2 |
| | Nasonex (Spray type allergic rhinitis remedy) | — | 1.3 | — | 4.1 | +4.1 | — | — | 10.1 | 10.1 |
| | Beova ※ (selective β3-adrenergic receptor agonist for the treatment of overactive bladder) | — | — | — | 0.7 | +0.7 | — | — | 0.8 | 0.8 |
| ※ released in November 2018 | | | | | | | | | | |
| Generic Drugs | MONTELUKAST Tablets "KM" | 5.0 | 5.3 | 8.2 | 8.3 | +0.1 | +1.3 | 11.7 | 9.8 | 9.8 |
| Over-the- counter drugs | Milton (Disinfectant) | 1.1 | 1.1 | 1.7 | 1.7 | 0 | +0.7 | 2.2 | 2.3 | 2.3 |

Main R&D Activities -1 (as of February 5 2019)

Ph III ~ Application submitted

※Changes from the previous announcement (Nov 5 2018)

| Stage | | Compound/ Code | Therapy area /Action | Origin | Features | Comments |
|-----------------------------------|----------|---------------------------------|--|-------------------|---|----------|
| Japan | Overseas | | | | | |
| 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 | |
| Preparing for Application | | KRP- AM1977Y (Injection) | New quinolone synthetic antibacterial agent | In-house | - Expectation of high clinical effects with excellent tissue penetration -High degree of safety expected since safety hurdles cleared prior to clinical trials | |
| Ph III (3/2017) | | KRP-116D | Interstitial cystitis | — | Evaluation committee on unapproved or off-labeled drugs with high medical needs “Dimethyl sulfoxide(DMSO)” | |
| ※ Preparing for Application | | KRP-108P | Anti-asthmatic | (U.K.) Vectura | Expand the indication of Flutiform to pediatric patients | |

※ Overactive bladder therapeutic agent "Beova tablets 50mg": released in November 2018

Main R&D Activities -2 (as of February 5 2019)

POC Project (Ph I ~ Ph II)

※Changes from the previous announcement (Nov 5 2018)

| Stage | | Compound/ Code | Therapy area /Action | Origin | Features | Comments |
|-------------------|----------|-----------------------|--|---|--|--|
| Japan | Overseas | | | | | |
| Ph II (8/2018) | | KRP-N118 (SK-1404) | Nocturia Due to Nocturnal Polyuria | SANWA KAGAKU KENKYUSHO 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) |
| Ph II (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) |

Segment information for the Third Quarter Ending March 31, 2019

Sales, Profit or Loss of each report segment

| (unit : ¥billion) | Sales | change Y/Y | Profit | change Y/Y |
|-------------------------------|-------------|-------------|------------|-------------|
| Net Sales (total) | 82.0 | -0.9 | 6.8 | -1.0 |
| Ethical drugs business | 77.6 | -0.9 | 6.3 | -1.0 |
| ◆Sales of new ethical drugs | 56.2 | -1.7 | | |
| ○Japan | 55.5 | +0.7 | | |
| ○Overseas | 0.6 | -2.5 | | |
| ◆Generic drugs | 21.4 | +0.8 | | |
| Healthcare business | 4.4 | 0 | 0.2 | 0 |
| Amount of adjustment | - | - | 0.3 | 0 |

Consolidated Financial Results for the Third Quarter ending March 31, 2019

| (unit : ¥million) | Sep/2017 | Sep/2018 | Dec/2017 | Dec/2018 | Change | % Y/Y | Mar/2018 | Mar/2019 (revised forecast) | Mar/2019 (original forecast) |
|-----------------------------------|----------|----------|----------|---------------|--------|-------|----------|-----------------------------------|------------------------------------|
| Sales | 50,758 | 50,360 | 82,923 | 82,017 | -906 | -1.1 | 110,640 | 110,600 | 114,400 |
| Ethical drugs business | 47,977 | 47,581 | 78,484 | 77,601 | -883 | -1.1 | 104,703 | 104,600 | 108,400 |
| ◆Sales of new ethical drugs | 34,972 | 34,028 | 57,902 | 56,165 | -1,737 | -3.0 | 77,041 | 77,100 | 80,900 |
| ●Japan | 34,449 | 33,424 | 54,798 | 55,535 | +737 | +1.3 | 73,702 | 76,100 | 79,900 |
| ●Overseas | 523 | 604 | 3,104 | 629 | -2,475 | -79.7 | 3,339 | 1,000 | 1,000 |
| ◆Generic drugs | 13,005 | 13,552 | 20,582 | 21,436 | +854 | +4.1 | 27,662 | 27,400 | 27,400 |
| healthcare business | 2,781 | 2,779 | 4,438 | 4,415 | -23 | -0.5 | 5,937 | 6,000 | 6,000 |
| Operating Income | 1,443 | 2,852 | 7,805 | 6,794 | -1,011 | -13.0 | 8,822 | 8,200 | 8,600 |
| Ordinary Income | 1,693 | 3,183 | 8,246 | 7,124 | -1,122 | -13.6 | 9,345 | 8,600 | 9,200 |
| Net Income | 1,240 | 2,217 | 6,119 | 5,112 | -1,007 | -16.5 | 6,574 | 6,100 | 6,600 |