Financial Results for Fiscal 2013

May 12, 2014
KYORIN Holdings, Inc.
President Masahiro Yamashita
Outline of Consolidated Financial Results

Trends of mainstay products

Status of development pipeline

Consolidated Financial Results Forecast and Dividends
Outline of Consolidated Financial Results
## Outline of Consolidated Financial Results for Fiscal 2013

(单位：十亿日元)

<table>
<thead>
<tr>
<th></th>
<th>FY2012</th>
<th>FY2013</th>
<th>Change</th>
<th>Change(%)</th>
<th>Change (forecast)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Net Sales</strong></td>
<td>107.0</td>
<td>111.4</td>
<td>+4.4</td>
<td>+4.1</td>
<td>-1.2</td>
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<tr>
<td><strong>Operating Income</strong></td>
<td>17.9</td>
<td>17.6</td>
<td>-0.3</td>
<td>-1.9</td>
<td>-0.6</td>
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<tr>
<td><strong>Ordinary Income</strong></td>
<td>18.7</td>
<td>18.3</td>
<td>-0.4</td>
<td>-2.1</td>
<td>-0.5</td>
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<tr>
<td><strong>Net Income</strong></td>
<td>12.4</td>
<td>12.0</td>
<td>-0.4</td>
<td>-3.2</td>
<td>-0.4</td>
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## Segment Sales

<table>
<thead>
<tr>
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<th>FY2012</th>
<th>FY2013</th>
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<tr>
<td><strong>Ethical drugs business</strong></td>
<td>105.2</td>
<td>109.7</td>
<td>+4.5</td>
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<tr>
<td>Sales of new ethical drugs</td>
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<tr>
<td>Japan</td>
<td>90.7</td>
<td>93.5</td>
<td>+2.8</td>
<td>+3.1</td>
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<tr>
<td>Overseas</td>
<td>2.4</td>
<td>1.8</td>
<td>−0.6</td>
<td>−22.9</td>
<td>−0.5</td>
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<tr>
<td><strong>Generic drugs</strong></td>
<td>10.1</td>
<td>12.0</td>
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<tr>
<td><strong>Over-the-counter drugs</strong></td>
<td>4.4</td>
<td>4.2</td>
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<td><strong>Healthcare Business</strong></td>
<td>1.9</td>
<td>1.7</td>
<td>−0.2</td>
<td>−7.8</td>
<td>0.0</td>
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</table>

### Explanation of Variances

**new ethical drugs(Japan)**
- Increased year on year due to Flutiform, fall below forecast (Fultiform, Mucodyne)
- Increase of royalty (licensing out product)
- Influence of KYORIN Pharmaceutical Facilities sales (full year)

**new ethical drugs(overseas)**
- Sales of Gatifloxacin decreased effect of generic product was launched in USA
- Sales of Allergan: FY12 $80MM → FY13 $61MM
- Expenses associated with the income due to transfer of Pekiron assets were posted in the previous year.

**Generic drugs**
- Increase of Health insurance pharmacy market’s sales and contract manufacturing’s sales
## Breakdown of Gain and Loss

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<tr>
<td><strong>Cost of Sales</strong></td>
<td>40.1</td>
<td>43.0</td>
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<td><strong>SG&amp;A</strong></td>
<td>48.9</td>
<td>50.7</td>
<td>+1.8</td>
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<td><strong>R&amp;D expenses</strong></td>
<td>11.1</td>
<td>11.4</td>
<td>+0.3</td>
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<tr>
<td><strong>SG&amp;A expenses</strong></td>
<td>37.9</td>
<td>39.4</td>
<td>+1.5</td>
<td>+4.0</td>
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### Explanation of Variances

**year on year**

- **gross profit**: increased ¥1.5bln
  (increase of sales ¥4.4bln, cost of sales ratio increased 1.1%)
  【reason for increase of cost of sales ratio】increase of generic drugs and KYORIN pharmaceutical Facilities sales
- **SG&A expenses**: Increased ¥1.8bln
  【reason for increase】R&D expense increased ¥0.3bln (progress of KRP-209 Ph2a), SG&A (exclude R&D) expense increased ¥1.5bln (increase of sales expenses, patent royalty etc.)

**compared to budget**

- **gross profit**: fall below forecast
  (sales fall below forecast, increase of cost of sales ratio)
  【reason for increase of cost of sales ratio】effect of exchange rate, low operating rate of facilities
- **SG&A Expenses**: fall below forecast
  【reason for increase】R&D expense decreased ¥0.4bln, reduced SG&A (exclude R&D) expense
**Highlights of Business Performance**

(Units: ¥ billion)

**Highlight ①**
- Net Sales increased ¥4.4 billion
  - Increase of Japan new ethical drugs and generic drugs sales
  - Effect of KYORIN pharmaceutical Facilities sales
  - Sales of royalty (licensing out product)

**Highlight ②**
- Cost of Sales ratio increased 1.1 percentage points (+¥2.9 bln)
- Gross Profit increased ¥1.5 billion

**Highlight ③**
- SG&A expenses increased ¥1.8 billion
  - R&D expenses increased ¥0.3 billion
  - SG&A (excluding R&D) increased ¥1.5 billion

- Operating Income decreased ¥0.3 billion
# Mainstay Product Sales

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<tr>
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<td>Kipres</td>
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<td>40.2</td>
<td>+0.6</td>
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<td>Mucodyne</td>
<td>19.1</td>
<td>18.4</td>
<td>−0.7</td>
<td>−4.0</td>
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<tr>
<td>Pentasa</td>
<td>17.6</td>
<td>18.6</td>
<td>+1.0</td>
<td>+5.3</td>
<td>+0.1</td>
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<tr>
<td>Uritos</td>
<td>7.5</td>
<td>8.1</td>
<td>+0.6</td>
<td>+7.9</td>
<td>+0.1</td>
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<tr>
<td>Flutiform</td>
<td>−</td>
<td>0.6</td>
<td>+0.6</td>
<td>—</td>
<td>−0.4</td>
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(unit: ¥billion)
Trends of mainstay products
Business Strategy (Strategy)

Multi-Core Strategy (MC Strategy)
—Diversify the Consumer Healthcare Business Centering on the Ethical Drug Business—

Ethical Drug Business

Pharma Complex Model
(PC model)
Multi-faceted business development
(New drugs, original drugs, generic drugs)

Consumer Healthcare Business
Cultivate existing businesses and create new businesses

Fiscal 2015:
Sales ¥140.0bln  Operating income ¥20.0bln

[sales breakdown] Ethical drugs ¥120.0bln (new drugs ¥50.0bln, original drugs ¥50.0bln, generic drugs ¥20.0bln)
Consumer Healthcare business ¥20.0bln
Ethical Drug Business

**New drugs group**
- Maximize uptake of Kipres, Uritos, Flutiform
- Enhance the Development Pipeline (KRP-AB1102)

**Original products group**
- Use LCM to raise value of focus products (Mucodyne, Pentasa) and extend lifecycle

**Generic drugs group**
- Promote domestic and overseas alliances to enhance product lineup and lower costs
- Leverage stronger ties within the KYORIN Group to promote a more distinctive generics business
- Promotion of collaborative development

**Pharma Complex Model (PC Model)**

<table>
<thead>
<tr>
<th>FY09</th>
<th>FY10</th>
<th>FY11</th>
<th>FY12</th>
<th>FY13</th>
<th>FY14 forecast</th>
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<td>49.5</td>
<td>48</td>
<td>44.9</td>
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<td>32.9</td>
<td>40</td>
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<tr>
<td>91.0</td>
<td>8.9</td>
<td>8.7</td>
<td>10.1</td>
<td>12</td>
<td>12.7</td>
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</tbody>
</table>

(unit: ¥billion)

LCM: Life Cycle Management
New drugs group
Flutiform [Anti-asthmatic]

status of FY2013

<table>
<thead>
<tr>
<th></th>
<th>Flutiform 50 Aerosol - 56 inhalations</th>
<th>Flutiform 50 Aerosol - 120 inhalations</th>
</tr>
</thead>
<tbody>
<tr>
<td>approval</td>
<td>September 2013</td>
<td>September 2013</td>
</tr>
<tr>
<td>launch</td>
<td>November 2013</td>
<td>December 2014 (scheduled date)</td>
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</table>

FY2013 sales: ¥0.6bln

effort for FY2014

FY2014 sales: ¥2.8bln

Aim for dramatic market penetration after the lifting of prescription limitations

- launch of a longer-term prescription formulation
  Flutiform 50 Aerosol - 120 inhalations, Flutiform 125 Aerosol - 120 inhalations

- Further promote prescription to partly controlled asthma patients
  ※Even if it has taken controller, 60 to 80% of the patients (treatment steps2~4) are Partly Controlled

- appeal advantages of pMDI device
**New drugs group**

**Kipres** 【Bronchial asthma and allergic rhinitis treatment】

(unit: ¥billion)

### status of FY2013

- **LT antagonists market**: expand 2%
  
  ¥125.1bln (FY2012) ⇒ ¥127.4 (FY2013) ※1

- **share of Kipres sales**
  
  34.9% (FY2012) ⇒ 36.0% (FY2013) ※2

### effort for FY2014

- **Establish position as base drug for treatment of allergic rhinitis (perennial and seasonal) and growth in new prescriptions**

- **Further promote prescription**
  
  ➢ price revision rate ▲7.4%

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New drugs group
Uritos 【Overactive bladder】

((unit : ¥billion)

■status of FY2013

◆ OAB market : expand 11%

¥70.4bln(FY2012) ⇒ ¥77.9bln(FY2013) ※1

◆ share of Uritos sales

11.4%(FY2012) ⇒ 10.9%(FY2013) ※2

■ effort for FY2014

Uncovering potential markets
FY14 : potential patient 9.2million people／consultation rate 30%

Pervading usability
prescriptions based on EBM (OAB patient with BPH ※3)

price revision rate ▲0.4%

※1,2 (Source:Copyright 2014 IMS JAPAN IMS—JPM. Unauthorized copying prohibited )
※3 benign prostatic hypertrophy
■ Original products group

**Mucodyne** 【Mucoregulating drug】

(status of FY2013)

- **expectorant market**: 3% reduction
  
  ¥44.9bn (FY2012) ⇒ ¥43.5bn (FY2013) ※1

- **share of Mucodyne sales**
  
  46.9% (FY2012) ⇒ 46.2% (FY2013) ※2

  share of generic (Carbocisteine)

  6.3% (FY2012) ⇒ 7.4% (FY2013) ※3

■ effort for FY2014

- **Maximize uptake and prescriptions of 「DS50%」**
  
  • prescriptions for upper airway

- **Increase prescriptions based on EBM**
  
  • bronchial asthma, chronic bronchitis
  
  chronic sinus infection etc.

  ➢ **price revision rate ▲6.9%**

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■ Original products group

Pentasa 【Ulcerative colitis and Crohn’s disease treatment】

(单位：¥ billion)

■ status of FY2013

◆ market (Mesalazine etc.): expand 12%
  ¥33.8 bln (FY2012) ⇒ ¥37.9 bln (FY2013) ※1

◆ share of Pentasa sales
  56.8% (FY2012) ⇒ 52.7% (FY2013) ※2

■ effort for FY2014

◆ market penetration of suppositories
  FY2013 ¥1.2 bln, FY2014 (forecast) ¥1.5

◆ prescription for ulcerative colitis active period
  • active period: prescription of 4g twice a day
  • remission period: prescription of 2g once a day

➢ price revision rate ▲ 7.5%

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**Generic drugs group**

**Status of Generic Drugs**

Sales (unit: ¥billion)

- FY09: 10.1
- FY10: 10.3
- FY11: 9.6
- FY12: 10.4
- FY13: 12.4
- FY14 forecast: 13.2

- **status of FY2013**
  - Sales: ¥12.4bn (+¥2.0bn)
    - expand of strategic products and supplementary Item
    - increase of contract manufacturing sales
  - Operating income: ¥1.0bn (+0.6bn)
    - R&D expense reduced by collaborative development

- **effort for FY2014**
  - Promotion of collaborative development
  - Sales
    - increase of strategic products and Supplementary Item
  - Operating income
    - Promotion of collaborative development
    - reducing R&D expense by collaborative development
    - accelerate contract manufacturing
Consumer Healthcare Business
(skin care + otc drugs and others)

effort for Medium-Term Business Plan
"HOPE 100 — Stage 1 —"

- **Skincare Business**
  Make business profitable and promote growth
  (including development in Asian market)

- **Milton Business, etc.**
  Leverage the Milton brand to develop new businesses

- **New Business Creation**
  Realize our corporate philosophy and create new businesses that can become the core of the company in the future (Environmental Hygiene Business etc.)

(unit: ¥billion)

<table>
<thead>
<tr>
<th>Year</th>
<th>FY09</th>
<th>FY10</th>
<th>FY11</th>
<th>FY12</th>
<th>FY13</th>
<th>FY14 forecast</th>
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<tr>
<td>Value</td>
<td>8.7</td>
<td>7.2</td>
<td>6.6</td>
<td>6.2</td>
<td>5.9</td>
<td>6.4</td>
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</table>
Environmental Hygiene business

promote spread of Disinfectant 「Milton」 and Multi-purpose disinfectant cleaner 「RUBYSTA」

● Disinfectant 「Milton」
  • Strengthen promotion targeting maternity hospitals  
    (increase new adoptions and gain understanding in mothers’ classes)
  • Grasp how the product is used in medical institutions and facilitate adoption as the in-hospital standard (double retailing with Rubysta).
  • FY2014 sales forecast: ¥2.0bln (FY2013: ¥2.1bln)

● Multi-purpose disinfectant cleaner 「RUBYSTA」
  • Aim at expanding use through introduction and standardization at hospitals while focusing on Category 1,2 facilities eligible for NHI points for measures against infections.
  • changing to self-manufacture
  • FY2014 sales forecast: ¥0.7bln (FY2013: ¥0.2bln)

● future effort
  • expand product lineup
    - kit product for helping prevent infection (July 2013 launched)
    - kit product of Multi-purpose disinfectant cleaner 「RUBYSTA」 for vomit (Dec 2013 launched)
  •
Status of development pipeline
## Drug Development Pipeline: Progress in FY2013

### Solid development in all areas of the R&D pipeline

<table>
<thead>
<tr>
<th>Product &amp; development code</th>
<th>Ph I</th>
<th>Ph II</th>
<th>Ph III</th>
<th>application</th>
<th>Approval/ Launch</th>
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<td><strong>Respiratory</strong></td>
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<tr>
<td>Fultiform</td>
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<td>▶ Nov launch (56 inhalations)</td>
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<td>KRP-AB1102</td>
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<td>▶ Mar application</td>
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<tr>
<td>Kipres Bronchial asthma (1~below the age of 15)</td>
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<td>KRP-209</td>
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<td><strong>Infections</strong></td>
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<td>Pentasa(UC) suppository</td>
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<td>KRP-203</td>
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### Progress in FY13
- Fultiform: Nov launch (56 inhalations)
- KRP-AB1102: Mar application
- KRP-AB1102F: Sep Ph III
- KRP-EPA605: Oct Ph I
- Kipres Bronchial asthma (1~below the age of 15): Apr Ph III
- KRP-209
- KRP-AM1977X: Sep Ph II
- KRP-AM1977Y
- Pentasa(UC) suppository: Jun launch
- KRP-203
Drug Development Pipeline: schedule of FY2014

Aim for an early advance to the next stage in “Respiratory” and “Infections”

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Aim to in-license products and collaborative development

- Nov launch (120 inhalations) Approval
- Ph III
- Ph II
COPD treatment agent : KRP-AB1102

■ KRP-AB1102

Action : Long-acting muscarine M3 antagonist (LAMA)
Active ingredient : Aclidinium Bromide
Formulation : Dry Powder Inhaler
Target disease : COPD
Dosage regimen : Inhaled by twice-a-day dosing
Origin : Almirall, S.A (Spain)

Features
• Fewer systemic side effects
• Twice-daily dosage improves symptoms and respiratory function throughout a day
• Short period reaching maximum effect
• Easy-to-use inhaler device

Reference
■ KRP-AB1102F

Fixed dose combination of LAMA and LABA (Long Acting Muscarinic Antagonist)
• LAMA : Aclidinium Bromide
• LABA : Formoterol
Tinnitus treatment agent : KRP-209

[Outline of clinical study]
• Phase II clinical study (double-blind study)
• Subjects: Patients with subjective tinnitus  Sample size: Approx. 400 patients
• Frequency of administration: Twice daily
• Endpoints: THI-12* etc. (changes from baseline at each assessment time point)

※ THI : Tinnitus handicap inventory

[Study result]
Significant improvements from previous values were recognized in all endpoints. However, no significant difference from the placebo group was observed.

[Future action]
A decision on future action will be made by the end of the second quarter of the fiscal year ending in March 2015.
Consolidated Financial Results Forecast and Dividends
# Consolidated Financial Results Forecast for the Year Ending March 31, 2015

<table>
<thead>
<tr>
<th></th>
<th>FY2013</th>
<th>FY2014 forecast</th>
<th>Change</th>
<th>Change(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Net Sales</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethical drugs business</td>
<td>111.4</td>
<td>112.2</td>
<td>+0.8</td>
<td>+0.7</td>
</tr>
<tr>
<td>Healthcare (skincare) Business</td>
<td>109.7</td>
<td>110.5</td>
<td>+0.8</td>
<td>+0.7</td>
</tr>
<tr>
<td></td>
<td>1.7</td>
<td>1.7</td>
<td>0.0</td>
<td>−1.3</td>
</tr>
<tr>
<td><strong>Operating Income</strong></td>
<td>17.6</td>
<td>15.8</td>
<td>−1.8</td>
<td>−10.3</td>
</tr>
<tr>
<td><strong>Ordinary Income</strong></td>
<td>18.3</td>
<td>16.3</td>
<td>−2.0</td>
<td>−10.8</td>
</tr>
<tr>
<td><strong>Net Income</strong></td>
<td>12.0</td>
<td>11.3</td>
<td>−0.7</td>
<td>−6.0</td>
</tr>
</tbody>
</table>

## Explanation of Variances

### Operating Income

<table>
<thead>
<tr>
<th>FY2014 Forecast</th>
<th>change</th>
<th>Explanation of Variances</th>
</tr>
</thead>
<tbody>
<tr>
<td>110.5</td>
<td>+0.8</td>
<td></td>
</tr>
</tbody>
</table>
| new ethical drugs (Japan) | 92.1 | +0.4 | • drug price revisions (in the 6% range for KYORIN Pharmaceutical),
| new ethical drugs (Overseas) | 1.0 | −0.8 | • decrease of Gatifloxacin (sales of Allergan: FY13 $61MM→FY14 $23MM) |
| Generic drugs   | 12.7   | +0.7 | • increase of Health insurance pharmacy market’s sales and contract manufacturing’s sales |
| Over-the-counter drugs | 4.6 | +0.4 | • Increase of Rubysta |

### Operating Income

<table>
<thead>
<tr>
<th>FY2014 Forecast</th>
<th>change</th>
<th>Explanation of Variances</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.8</td>
<td>−1.8</td>
<td></td>
</tr>
</tbody>
</table>

- **gross profit**
- Decrease year on year, effect of cost of sales ratio (increase approximately 1% year on year)
- [reason for increase of cost of sales ratio] drug price revisions, decrease of Gatifloxacin, increase of generic product
- R&D expense: ¥12.5bn (+¥1.1bn year on year) progress of pipeline (KRP-AB1102F, KRP-AM1977X etc.)
- SG&A Expenses (excluding R&D Expenses)
- R&D ratio decrease approximately 1% year on year
# Forecast of Mainstay Product Sales

(unit: ¥billion)

<table>
<thead>
<tr>
<th>Product</th>
<th>FY2013</th>
<th>FY2014 Forecast</th>
<th>Change</th>
<th>Change(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kipres</td>
<td>40.2</td>
<td>40.3</td>
<td>+0.1</td>
<td>+0.4</td>
</tr>
<tr>
<td>Mucodyne</td>
<td>18.4</td>
<td>16.0</td>
<td>−2.4</td>
<td>−12.7</td>
</tr>
<tr>
<td>Pentasa</td>
<td>18.6</td>
<td>17.5</td>
<td>−1.1</td>
<td>−5.8</td>
</tr>
<tr>
<td>Uritos</td>
<td>8.1</td>
<td>8.2</td>
<td>+0.1</td>
<td>+2.1</td>
</tr>
<tr>
<td>Flutiform</td>
<td>0.6</td>
<td>2.8</td>
<td>+2.2</td>
<td>+390.3</td>
</tr>
</tbody>
</table>
Shareholder Returns

Basic Policy
The Company seeks to enhance its management base by balancing investments for growth and business continuity with shareholder returns. To this end, the Company aims for a consolidated payout ratio to shareholders of 30%.

<table>
<thead>
<tr>
<th>Net Income</th>
<th>FY2013 (forecast)</th>
<th>FY2013</th>
<th>FY2014 (forecast)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Income</td>
<td>¥12.4bln</td>
<td>¥12.0bln</td>
<td>¥11.3bln</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dividends</th>
<th>FY2013 (forecast)</th>
<th>FY2013</th>
<th>FY2014 (forecast)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dividend per share (Yen)</td>
<td>¥52.00 (interim ¥10.00)</td>
<td>¥52.00 (interim ¥10.00)</td>
<td>¥52.00 (interim ¥20.00)</td>
</tr>
<tr>
<td>Consolidated payout ratio(%)</td>
<td>31.2%</td>
<td>32.3%</td>
<td>34.4%</td>
</tr>
</tbody>
</table>