

**FY ending December 2013**  
**Third quarter results presentation**

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*This document contains certain forward-looking statements relating to such items as the company's (including its domestic and overseas subsidiaries) forecasts, targets and plans. These forward-looking statements are based upon information available to the company at the present time and upon reasonable assumptions made by the company in making its forecasts, but actual results in practice may differ substantially due to uncertain factors.*

*These uncertain factors include, but are not limited to, potential risks associated with the pharmaceutical industry's domestic and international operating environment, intellectual property risks, the risk of adverse reactions to pharmaceutical products, legal risks, risks arising from product manufacturing deficiencies, risks due to fluctuations in the market prices of raw materials, fuel and products, as well as exchange rate and financial market volatility.*

*This document contains information on pharmaceutical products (including products under development), but its contents should not be construed as promotion, advertising or as a medical recommendation*

# Summary of Q3 results (consolidated)

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Sales and profits increased in Q3 driven by a good performance by pharmaceutical products in Japan, continued strong growth at ProStrakan, and further weakening of the yen

| (Unit: ¥bn)                            | FY 2012 Q3      | FY 2013 Q3      | Change | FY2013 Forecast | Rate of progress |
|--|-----------------|-----------------|--------|-----------------|------------------|
| Net sales                              | 244.6           | 252.1           | +7.4   | 339.0           | 74.4%            |
| Operating income<br>(Operating margin) | 37.3<br>(15.3%) | 41.4<br>(16.4%) | +4.0   | 51.0            | 81.2%            |
| Ordinary income                        | 32.5            | 39.2            | +6.6   | 48.0            | 81.7%            |
| Net income                             | 15.4            | 23.3            | +7.8   | 28.0            | 83.3%            |

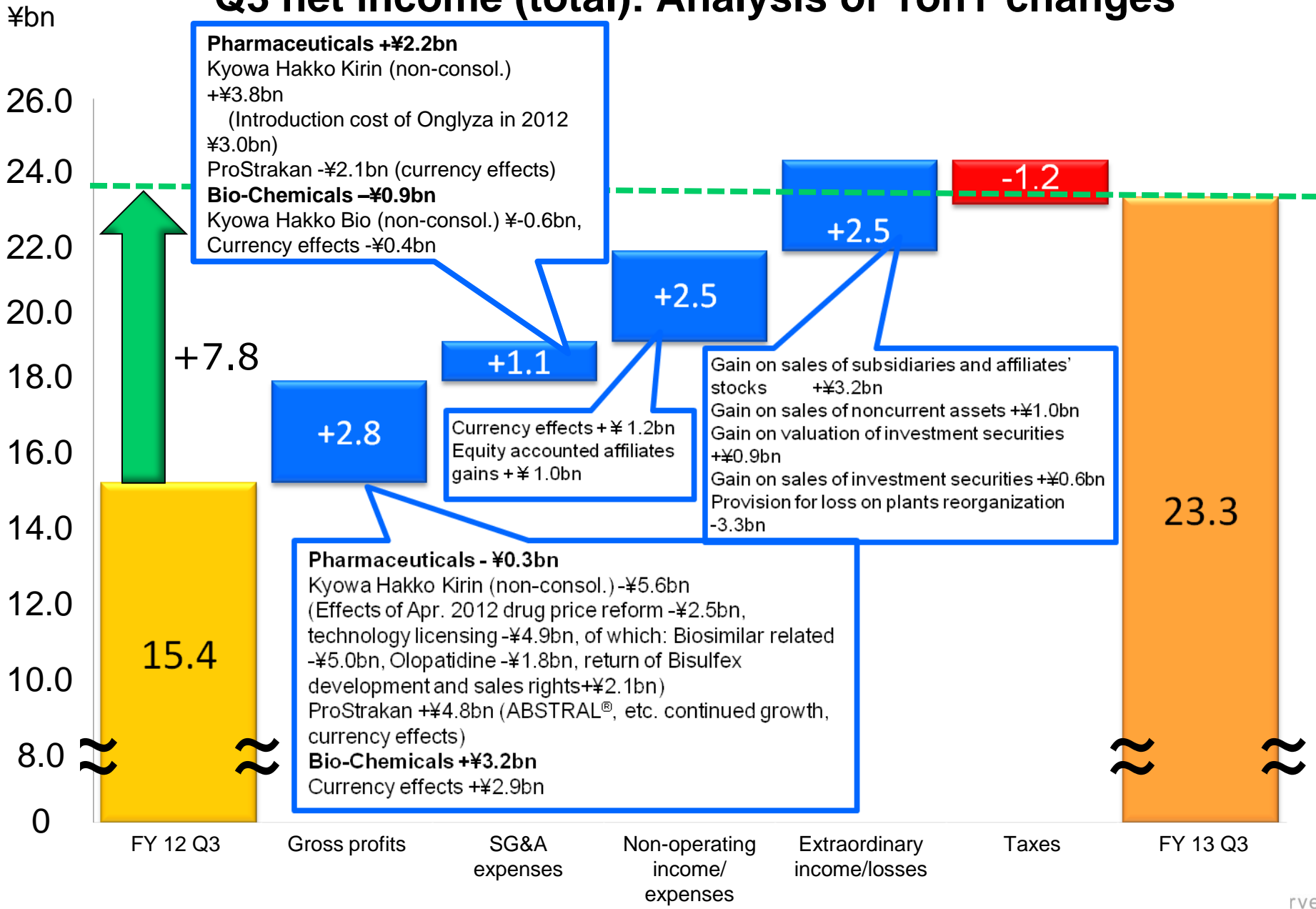
✓Growth in ordinary income was the result of higher operating income as well as forex gains and lower losses from equity-accounted affiliates

✓The increase in net income was the result of extraordinary income including gains on sale of related companies' shares

(Profits are stated after amortization of goodwill)

# Summary of Q3 consolidated results: Analysis of YonY profit changes

## Q3 net income (total): Analysis of YonY changes



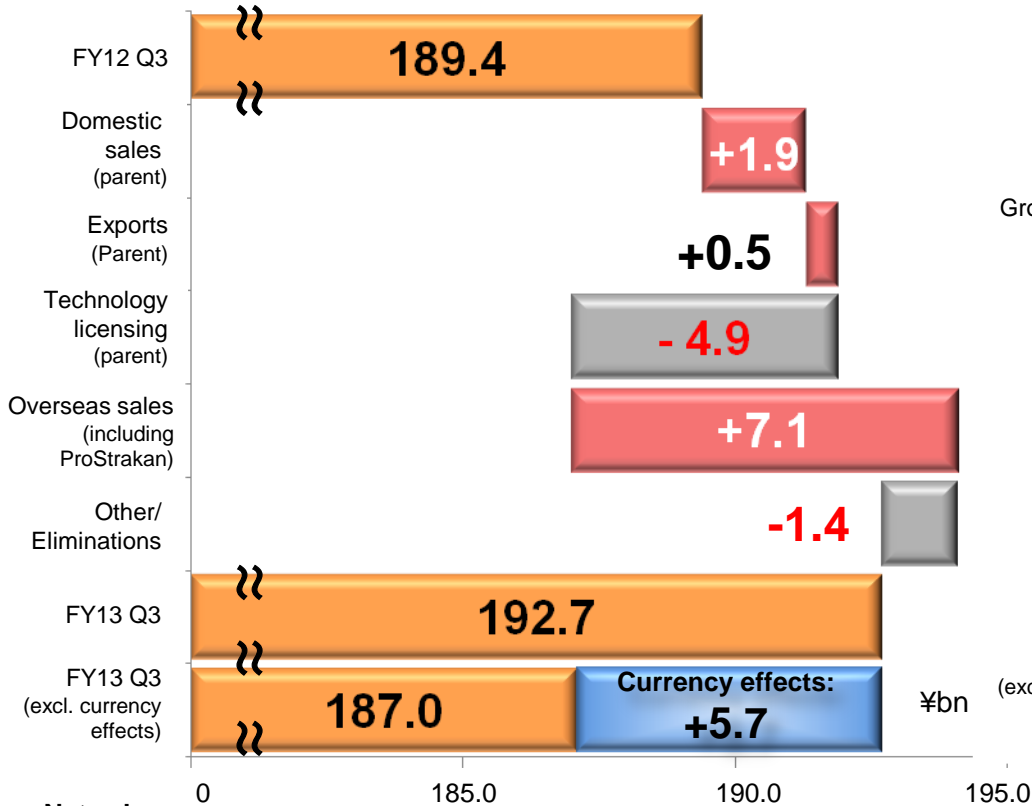
# Pharmaceuticals Business: Q3 results

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# Pharmaceuticals Business: Q3 results: Analysis of YonY profit changes

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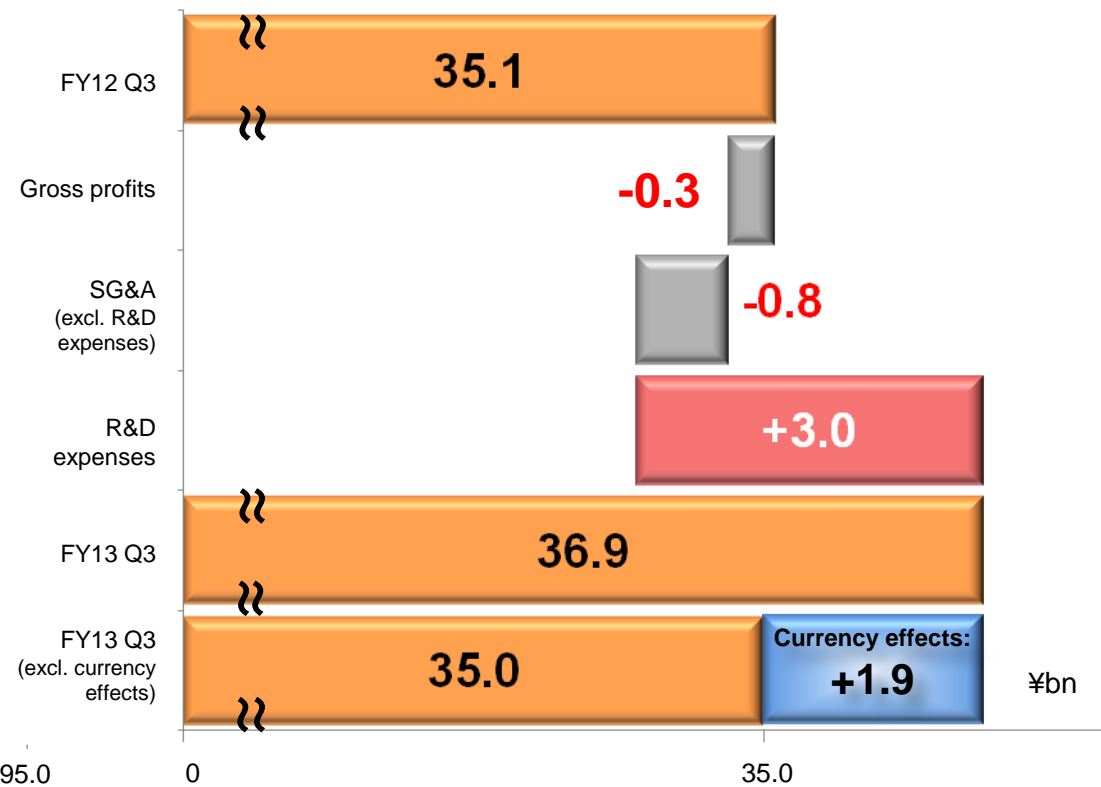
## Net sales



### Net sales

- Domestic pharmaceutical products (+¥1.9bn):
  - Products (shipments): Patanol®+¥2.9bn, REGPARA® +¥1.1bn, Asacol®+¥0.9bn, Romiplate® +¥0.5bn, Fentos® +¥0.4bn, NESP®-¥1.9bn, CONIEL®-¥1.1, ALLELOCK® -¥0.9, GRAN®-¥0.8bn
  - NESP : Sales declined due to lower shipments following launch of unified dosage product last year, reductions in NHI drug prices. Our share was maintained.
- Exports (+¥0.5bn): Currency effects, etc.
- Technology licensing (-¥4.9bn): Currency effects +¥1.0bn
- Biosimilars related (- ¥5.0bn), etc.
- Overseas sales (+¥7.1bn): Currency effects +¥4.0bn
- ProStrakan +¥5.1bn (forex +¥2.5bn), remainder Asia sales.

## Consolidated operating income



### Operating income

- Gross profits (-¥0.3bn):
  - Lower profits, resulting from the effects of NHI drug price cuts, a fall in licensing income from biosimilars, and other factors, could not be offset by ProStrakan's growth
- SG&A (-¥0.8bn)
  - A factor in the YOY decrease was the introduction cost of Onglyza (-¥3.0bn) in 2012. An increasing factor was currency effects at ProStrakan and other overseas distributors
- R&D expenses (+¥3.0bn):
  - Decrease in depreciation, and amortization expenses, and development costs

# Domestic sales of core pharmaceutical products

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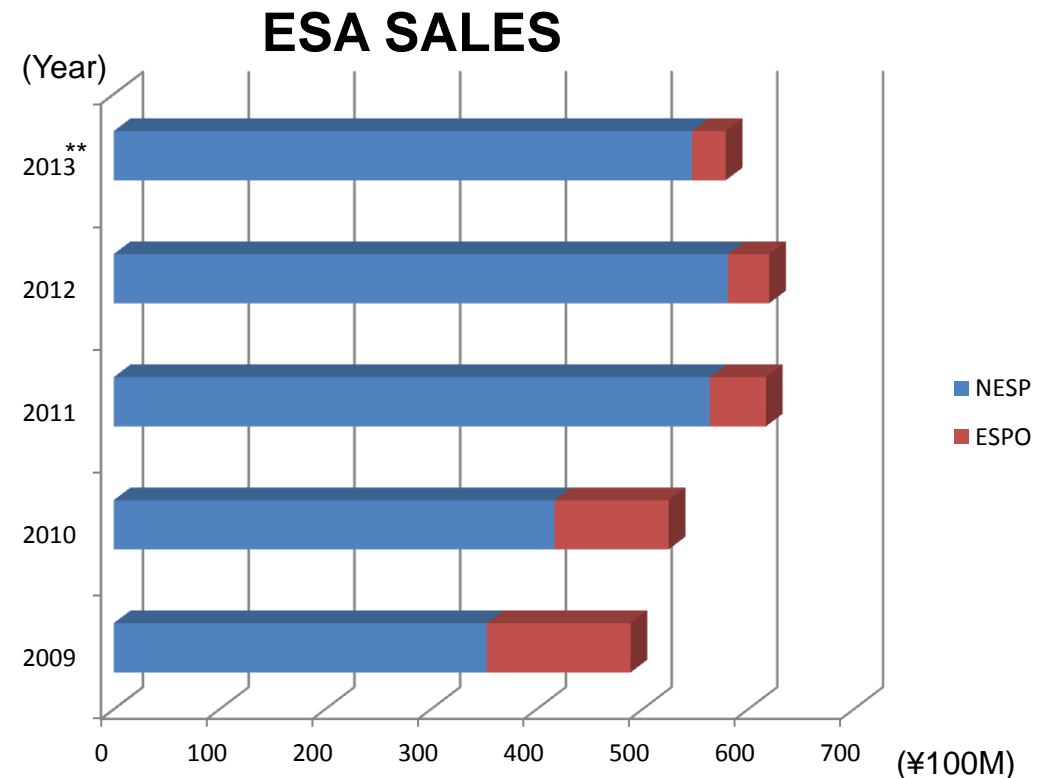
Domestic core pharmaceutical products on track to achieve 2013 full-year forecast despite impact of April 2012 reductions in NHI drug prices

| Product name             | Jan. – Sept.<br>2012<br>Results (a)* | Jan. – Sept.<br>2013<br>Results (b)* | Change*<br>(b)-(a) | Reason for changes   | Rate of<br>progress** |
|--------------------------|--------------------------------------|--------------------------------------|--------------------|--|-----------------------|
| NESP®                    | 41.0                                 | 39.1                                 | -1.9               | Impacted by lower shipments following launch of unified dosage product at end of 2012<br>Strong performance in recent months | 71.5%                 |
| REGPARA®                 | 9.5                                  | 10.6                                 | 1.1                | Steady market penetration  | 73.6%                 |
| ALLELOCK®                | 21.8                                 | 20.9                                 | -0.9               | Increase in pollen count<br>Impacted by market penetration of generics   | 76.0%                 |
| Patanol®                 | 8.5                                  | 11.4                                 | 2.9                | Increase in pollen count<br>Top share in anti-allergy eye drops  | 84.4%                 |
| GRAN®                    | 9.8                                  | 9.0                                  | -0.8               | G-CSF market contraction<br>Impacted by launch of biosimilars  | 73.2%                 |
| Exports                  | 7.5                                  | 8.1                                  | 0.5                | Currency effects   | 82.7%                 |
| Technology out-licensing | 18.9                                 | 13.8                                 | -5.1               | Decline in licensing income in biosimilar business   | 92.6%                 |



## Strong support from healthcare professionals as the easiest-to-use ESA\* No. 1 ESA market share in Japan

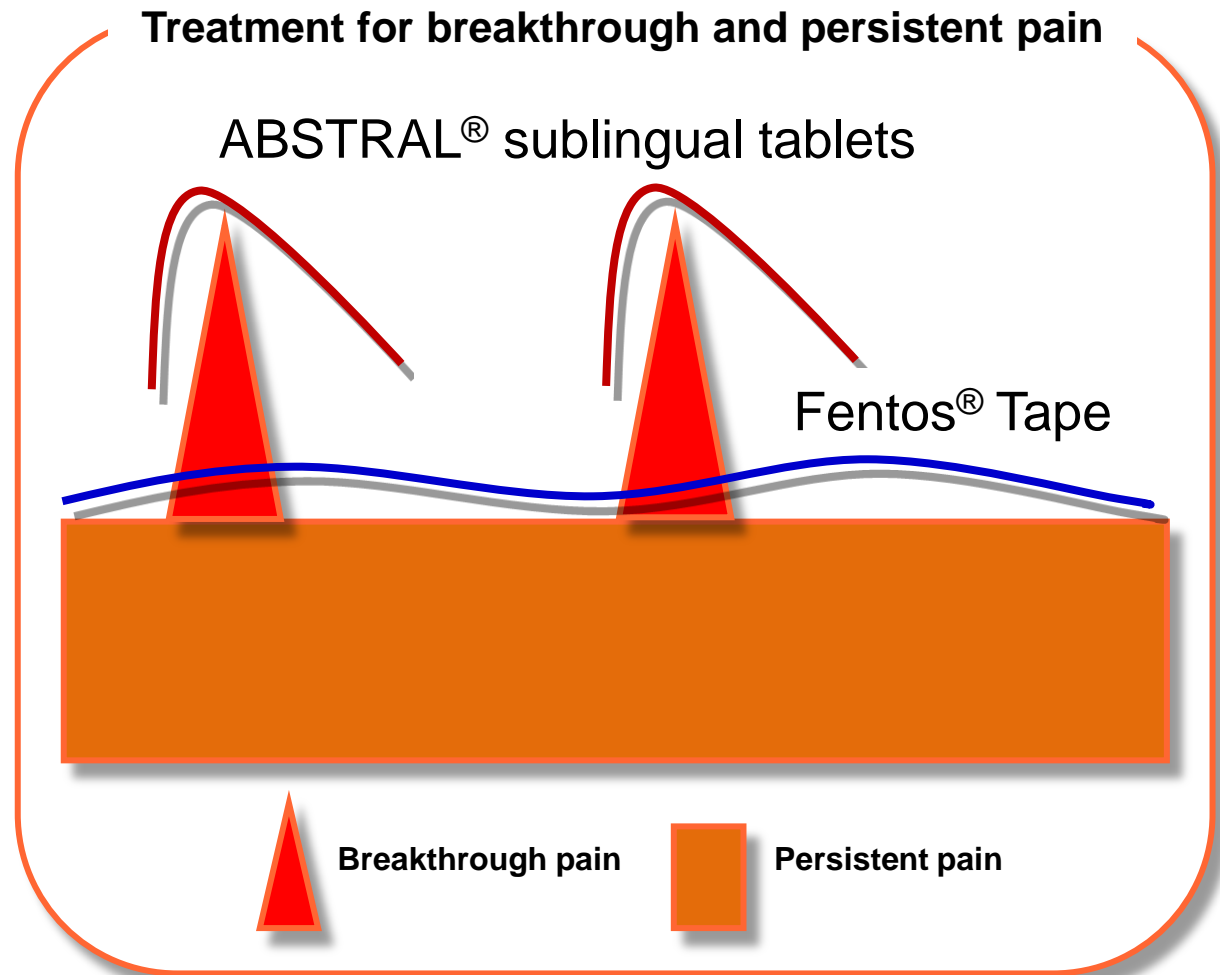
- The only long-lasting ESA that covers all renal anemia patients ranging from infants to adults and from pre-dialysis phase to dialysis phase
- One dose per week during the dialysis phase, 2-4 doses per week during pre-dialysis phase
- Launch of the NESP® injection 5µg Plastic Syringe has allowed improved management of anemia
- Standardization of liquid dose has contributed to improved convenience in the pre-dialysis phase
- Innovative plastic syringe has helped differentiation



**Have created Japan's only MR organization focused on the renal domain to meet customer needs for information**

The approval of ABSTRAL<sup>®</sup> fentanyl formulation makes it possible to consistently control persistent and breakthrough cancer pain and contribute to palliative cancer treatment.

- Cancer pain drug ABSTRAL<sup>®</sup> approved in Japan in September
- ABSTRAL<sup>®</sup> is the first sublingual tablet approved in Japan with fentanyl as the active ingredient
- ABSTRAL<sup>®</sup> is currently being marketed by ProStrakan in EU
- Strengthening promotional activities for ABSTRAL<sup>®</sup> by leveraging the expertise gained in cancer pain treatment, including at ProStrakan.



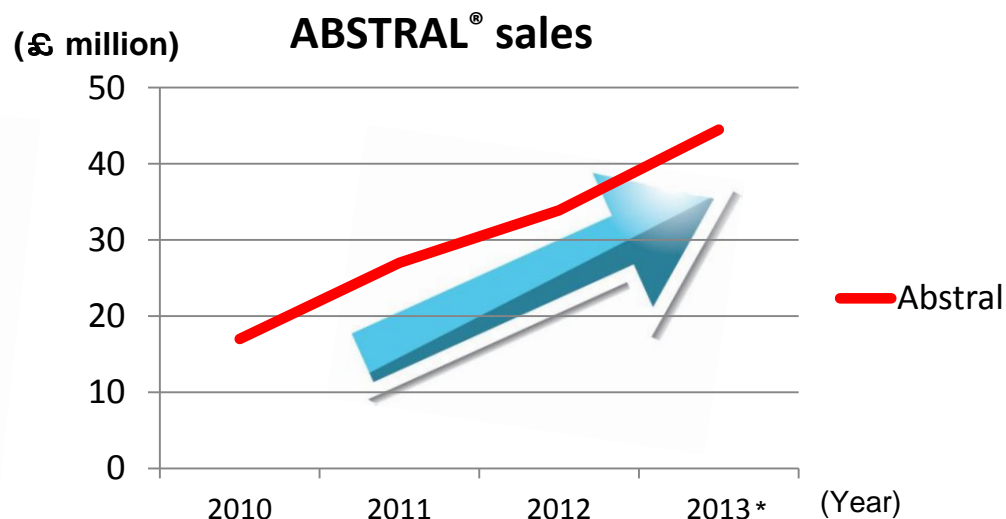
**Strong growth in ABSTRAL<sup>®</sup> sales, SANCUSO<sup>®</sup> launched in Europe  
Full year results from ProStrakan should make a positive contribution to  
consolidated Kyowa Hakko Kirin results**

## ABSTRAL<sup>®</sup>

- Nine-month sales up 140% YoY
- Achieved 77.1% of full year sales plan in first nine months

## SANCUSO<sup>®</sup>

- Launched in the UK, Germany and Holland, also plan launch in Norway in 2013
- Plans to launch in other EU countries from 2014



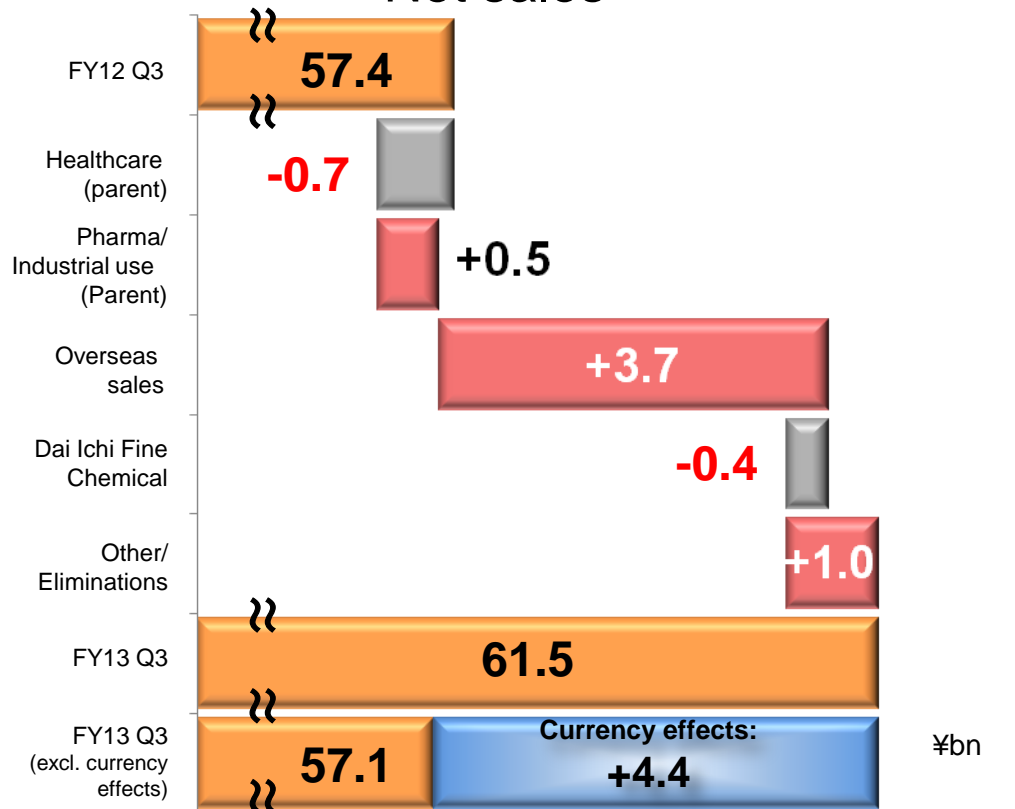
\*2013: Forecast figures

## Bio-Chemicals Business: Q3 results

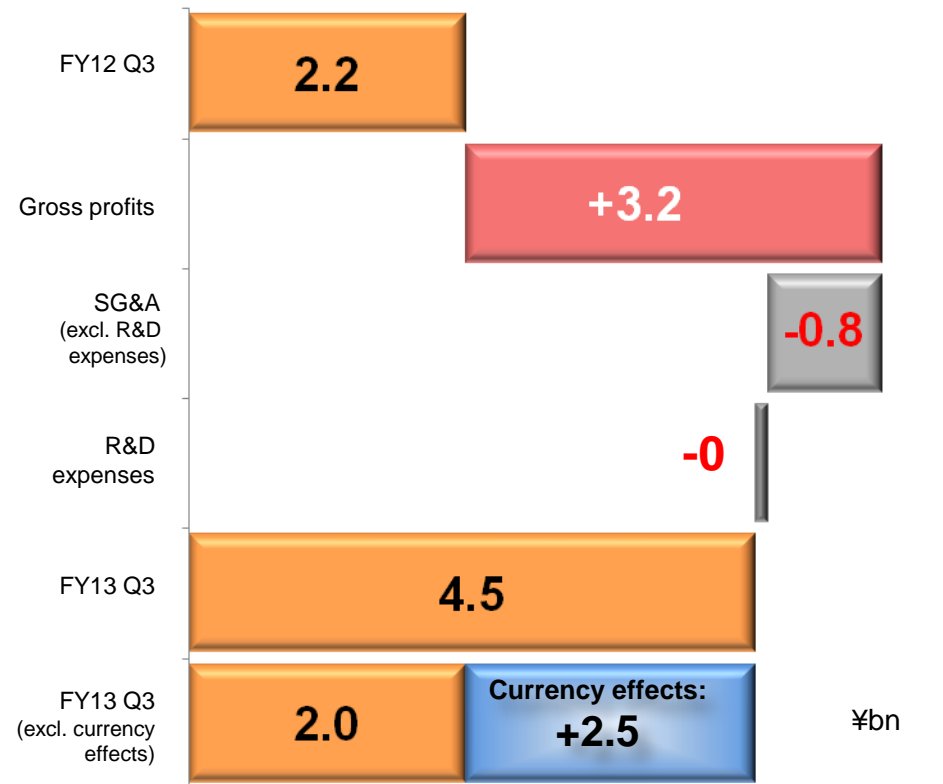
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# Bio-Chemicals Business: Q3 results: Analysis of YonY profit changes

## Net sales



## Consolidated operating income



### Net sales

- Healthcare (-¥0.7bn):
  - Mail order sales increased from same period in the previous year
  - Raw materials/OEM sales of amino acids for beverages sluggish, etc.
- Pharma/ Industrial use (+¥0.5bn): Raw materials for generic pharmaceuticals strong, etc.
- Overseas sales (+¥3.7bn): currency effects +¥4.4bn
  - U.S.: Currency effects (+0.9), impact of intensifying competition in sales of some raw materials for supplements (-0.2)
  - Europe: Currency effects (+1.9), decline in demand accompanying customer production timing in industrial-use products (-0.3)
  - Asia and others: Currency effects (+1.5), some pharmaceutical raw materials were sluggish and impact of intensifying competition in sales of some products (-0.2),
- Daiichi Fine Chemical (-¥0.4): Delay of shipments of Transexamic acid planned for this year, etc. (-0.4),

### Operating income

- Gross profits (+¥3.2bn): Currency effects +¥2.9bn
- SG&A(-¥0.8bn): Impact of exchange rates on overseas distributors and increases marketing expenses on mail order

# Development Pipeline

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**Application for approval in Japan for additional indication to maximize the value of POTELIGEO®**  
**Approvals for ABSTRAL® and NESP® progressing as planned**

## Japan

- ✓ **Application for additional indication for POTELIGEO®, a humanized anti-CCR4 monoclonal antibody (July 2013)**
  - Untreated CCR4-positive adult T-cell leukemia-lymphoma (ATL)
  - Relapsed or refractory CCR4-positive peripheral T-cell lymphoma (PTCL)
  - Relapsed or refractory CCR4-positive cutaneous T-cell lymphoma (CTCL)
- ✓ **Application for ABSTRAL®, a treatment of cancer pain, was approved (September 2013)**
- ✓ **Approvals for additional pediatric indications for NESP®, a treatment for renal anemia, and for the 5µg Plastic Syringe were received (September 2013)**

## License to develop and commercialize KRN23 with US-based company Ultragenyx Aiming to launch clinical trials for pediatric XLH\* in 2014

### Ultragenyx Pharmaceutical Inc.

**Business:** Established in 2010, specializing in therapeutic drug development for rare metabolism-related heredity diseases (unlisted company)

**CEO and President:** Emil D. Kakkis M.D., Ph.D.

**Location:** Novato, California, U.S.A.



### Details of collaboration

- **Parties to collaborate on development and commercialization in USA, Canada, and EU.**
  - Ultragenyx to lead development efforts in the XLH indication.
  - Parties to share development costs.
- **Parties to share commercial responsibilities and profits in USA and Canada.**
- **Kyowa Hakko Kirin responsible for commercialization in the EU.**
- **Ultragenyx responsible for development and commercialization in Mexico and Central & South America.**

\* X-linked hypophosphatemia (XLH)

Due to excessive concentrations of FGF23 in the blood, phosphate is wasted in the urine leading to hypophosphatemia resulting in a rare disease characterized by poor bone growth and mineralization.



## KRN23: Fully human antibody targeting FGF23

### Mechanism of action

- (1) KRN23 a therapeutic antibody that is designed to bind to FGF23, a biogenic factor that induces profound reductions in serum phosphate levels, thereby reducing the biologic activity of FGF23.
- (2) In contrast to current treatment with phosphate and vitamin D drugs, which increase the supply of phosphate to the body, KRN23 raises phosphate levels in the blood by inhibiting excessive excretion by the kidneys.

### Target disease

X-linked hypophosphatemia

Hereditary form of rickets in which phosphate concentrations in the blood are low from birth, leading to poor bone growth and degeneration.

| Estimated cases* | Adult  | Child |
|------------------|--------|-------|
| U.S.             | 12,000 | 3,000 |
| Europe           | 24,000 | 6,000 |

\*Estimate based on reported prevalence of 1 in 20,000 people

### Remarks

- **Origin: In-house product**
- **Antibody technique: Use of Kyowa Hakko Kirin KM mouse**

## MEDI-563

- Benralizumab
- Humanized anti-IL-5 receptor antibody
- AstraZeneca and MedImmune are conducting Phase II trials targeting asthma patients and Phase II trials targeting COPD patients

## FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.

## FKB327

- Adalimumab (Humira) Biosimilar drug
- Phase I trials underway in UK from H1 2013

## FKB238

- Bevacizumab (Avastin) Biosimilar drug
- Non-clinical trials now underway in order to begin clinical trials in 2014

# **KYOWA KIRIN**

**If you have any inquiries regarding this presentation please call:  
Corporate Communications Department, Kyowa Hakko Kirin Co., Ltd.**

**Tel: +81-3-3282-0009**

# Appendix

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## ARQ 197

### Promoting development of hepatocellular carcinoma in large Asian market

| Target disease |           | Stage  | Status       | Remarks  |
|----------------|-----------|--------|--------------|--|
| NSCLC          | EGFR-Wild | Phase3 | Discontinued | Occurrence of interstitial lung disease in the study       |
| NSCLC          | EGFR-Mut. | Phase2 | On going     | EGFR-Mut. common among Asians                              |
| Gastric cancer |           | Phase2 | On going     | High frequency among Asian people, including Japanese      |
| HCC            |           | Phase1 | On going     | High prevalence in Asia. Planning a multi-national study . |

## RTA 402

### Changing the development strategy based on the study results in Japan/overseas

| Target disease |          | Stage  | Status    | Remarks                             |
|----------------|----------|--------|-----------|-------------------------------------|
| CKD            | Type2 DM | Phase2 | Suspended | Revisiting development plan in 2013 |

(as of October 18, 2013)

# Development progress with outlicensed compounds

| Name                       | Partner   | Phase    |    |     | Remarks   |
|----------------------------|-----------|----------|----|-----|---|
|                            |           | I        | II | III |   |
| Tivozanib                  | AVEO      |          |    |     | Cancer<br>(VEGF receptor inhibitor)<br>(KRN951)                 |
| Benralizumab<br>(MEDI-563) | MedImmune |          |    |     | Asthma<br>(Anti-IL-5R antibody)<br>(KHK4563)<br>POTELLIGENT®    |
|                            |           |          |    |     | COPD  |
| KRN5500                    | DARA      |          |    |     | Peripheral neuropathy   |
| RGI2001                    | REGiMMUNE | Phase1/2 |    |     | Immunosuppressive   |
| SAR252067                  | Sanofi    |          |    |     | Ulcerative colitis and Crohn's disease<br>(anti-LIGHT antibody) |

(as of October 18, 2013)

## Forex rates (period average)

|      | 2012<br>Jan. – Sept. | 2013<br>Jan. – Sept. | YoY  |
|------|----------------------|----------------------|------|
| US\$ | ¥79                  | ¥95                  | +¥16 |
| EUR  | ¥102                 | ¥125                 | +¥23 |
| GBP  | ¥125                 | ¥147                 | +¥22 |

## Currency effects

|                  | 2013 Jan. – Sept. Currency effects (Year on year) |               |              |
|------------------|---|---------------|--------------|
|                  | Pharmaceuticals                                   | Bio-Chemicals | Consolidated |
| Net sales        | +¥5.7bn   | +¥4.4bn       | +¥10.2bn     |
| Operating income | +¥1.9bn   | +¥2.5bn       | +¥4.5bn      |