KYOWA KIRIN

FY ending December 2013

Third quarter results presentation

Kazuyoshi Tachibana
Executive Managing Officer and CFO

Kyowa Hakko Kirin Co., Ltd.

October 25, 2013

Forward-looking statements

KYOWA KIRIN

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)

Summary of Q3 results (consolidated)

KYOWA KIRIN

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 (Operating margin)	37.3 (15.3%)	41.4 (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

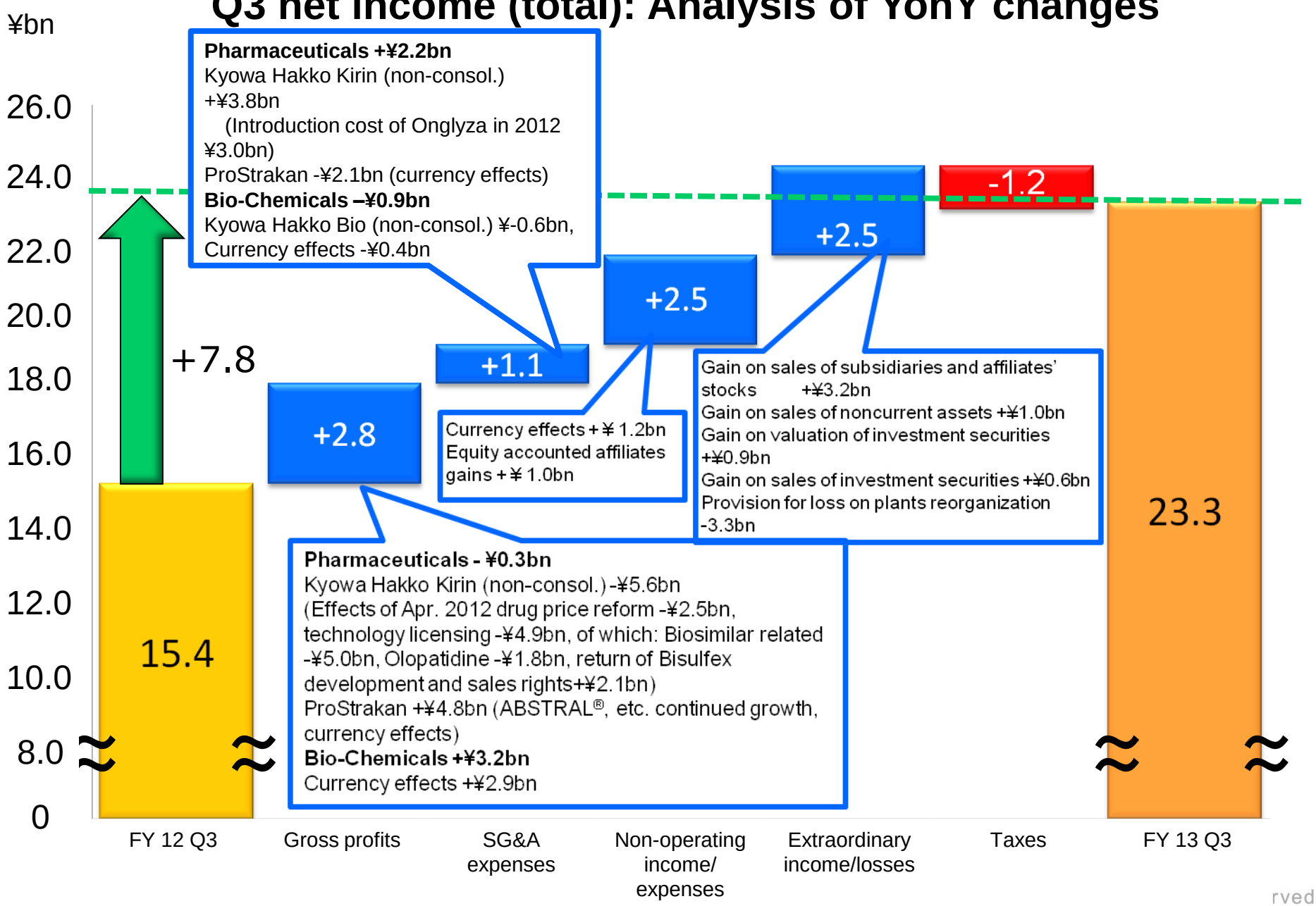
✓The increase in net income was the result of extraordinary income including gains on sale of related companies' shares

(Profits are stated after amortization of goodwill)

Summary of Q3 consolidated results: Analysis of YonY profit changes

KYOWA KIRIN

Q3 net income (total): Analysis of YonY changes

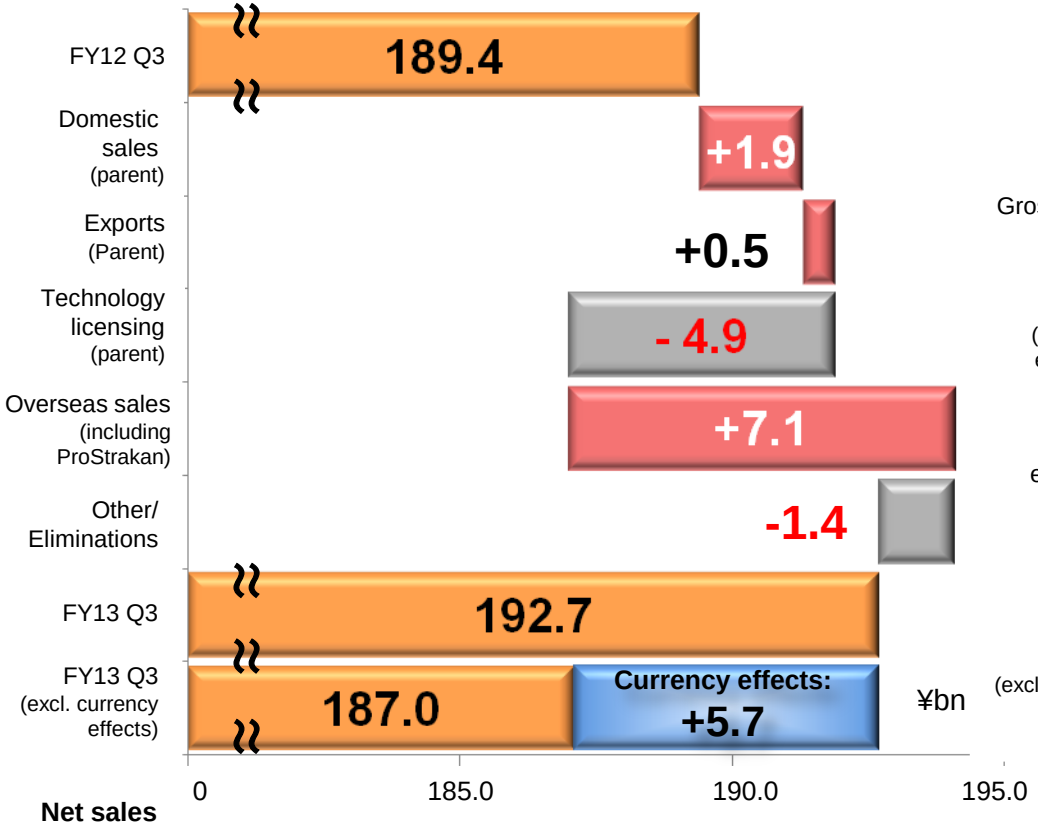


Pharmaceuticals Business: Q3 results

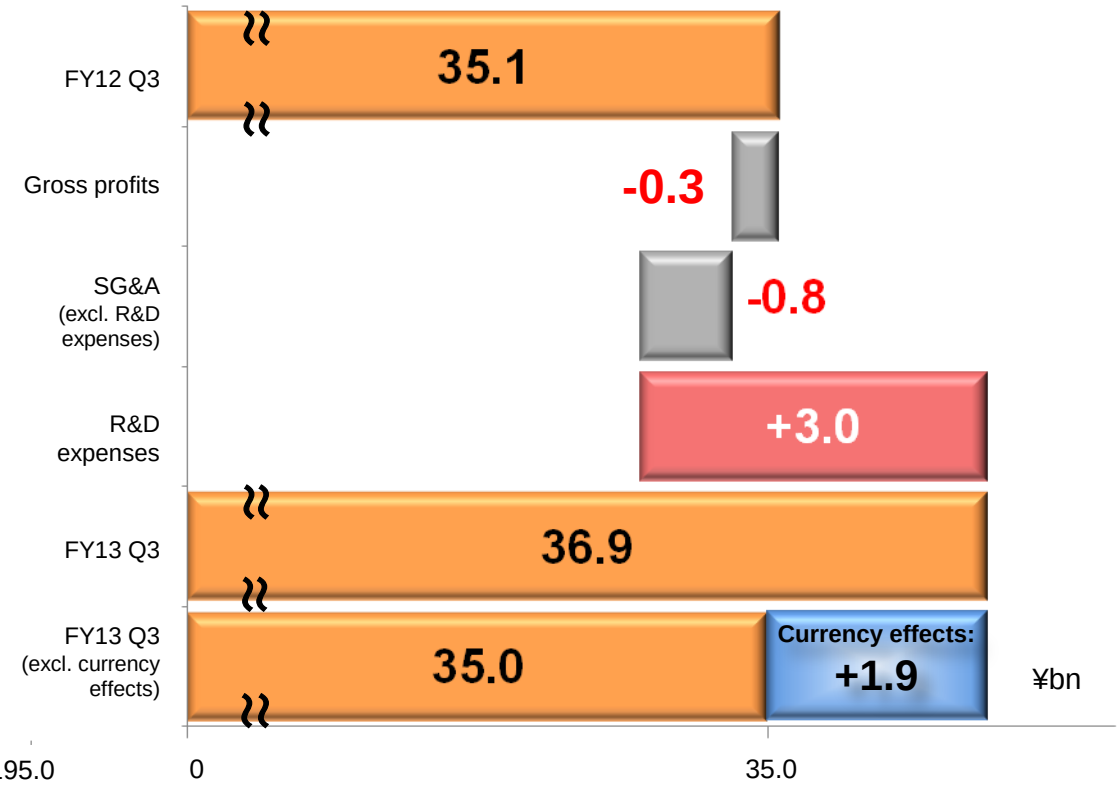
Pharmaceuticals Business: Q3 results: Analysis of YonY profit changes

KYOWA KIRIN

Net sales



Consolidated operating income



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.

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 Y0Y 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

KYOWA KIRIN

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. 2012 Results (a)*	Jan. – Sept. 2013 Results (b)*	Change* (b)-(a)	Reason for changes	Rate of progress**
NESP®	41.0	39.1	-1.9	Impacted by lower shipments following launch of unified dosage product at end of 2012 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 Impacted by market penetration of generics	76.0%
Patanol®	8.5	11.4	2.9	Increase in pollen count Top share in anti-allergy eye drops	84.4%
GRAN®	9.8	9.0	-0.8	G-CSF market contraction 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%

*Billions of yen

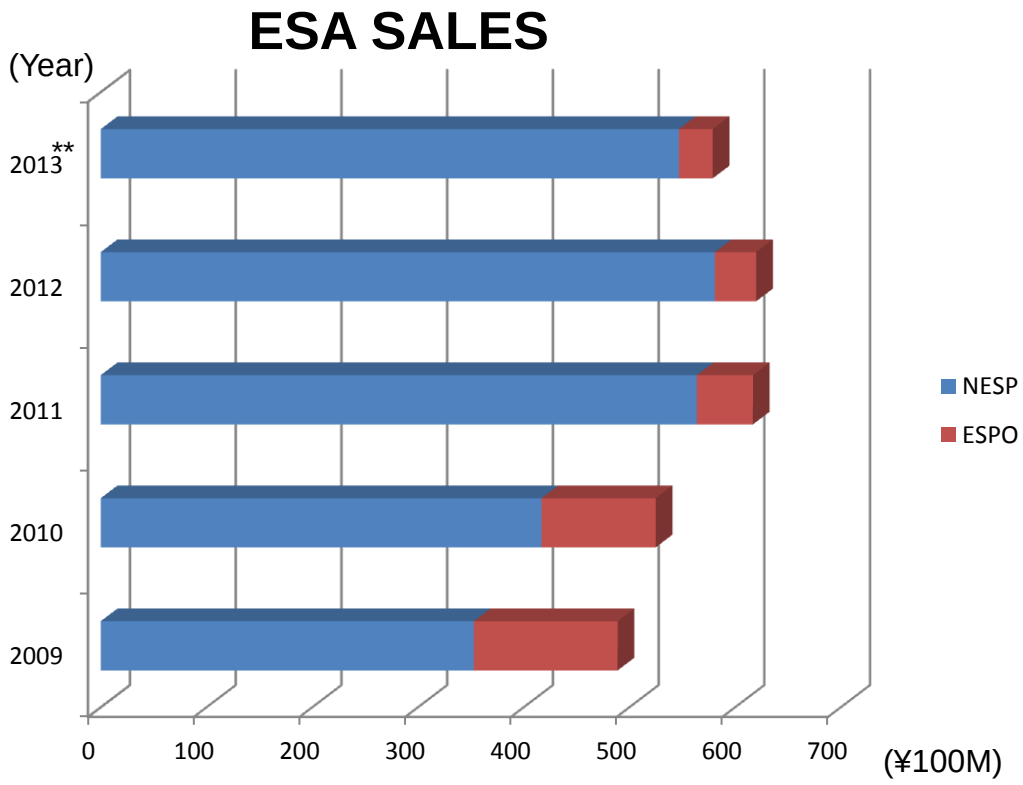
**Rate of progress compared to 2013 sales forecast. Figures rounded down.

Strengthening presence of NESP®

KYOWA KIRIN

**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

*Erythropoiesis Stimulating Agent

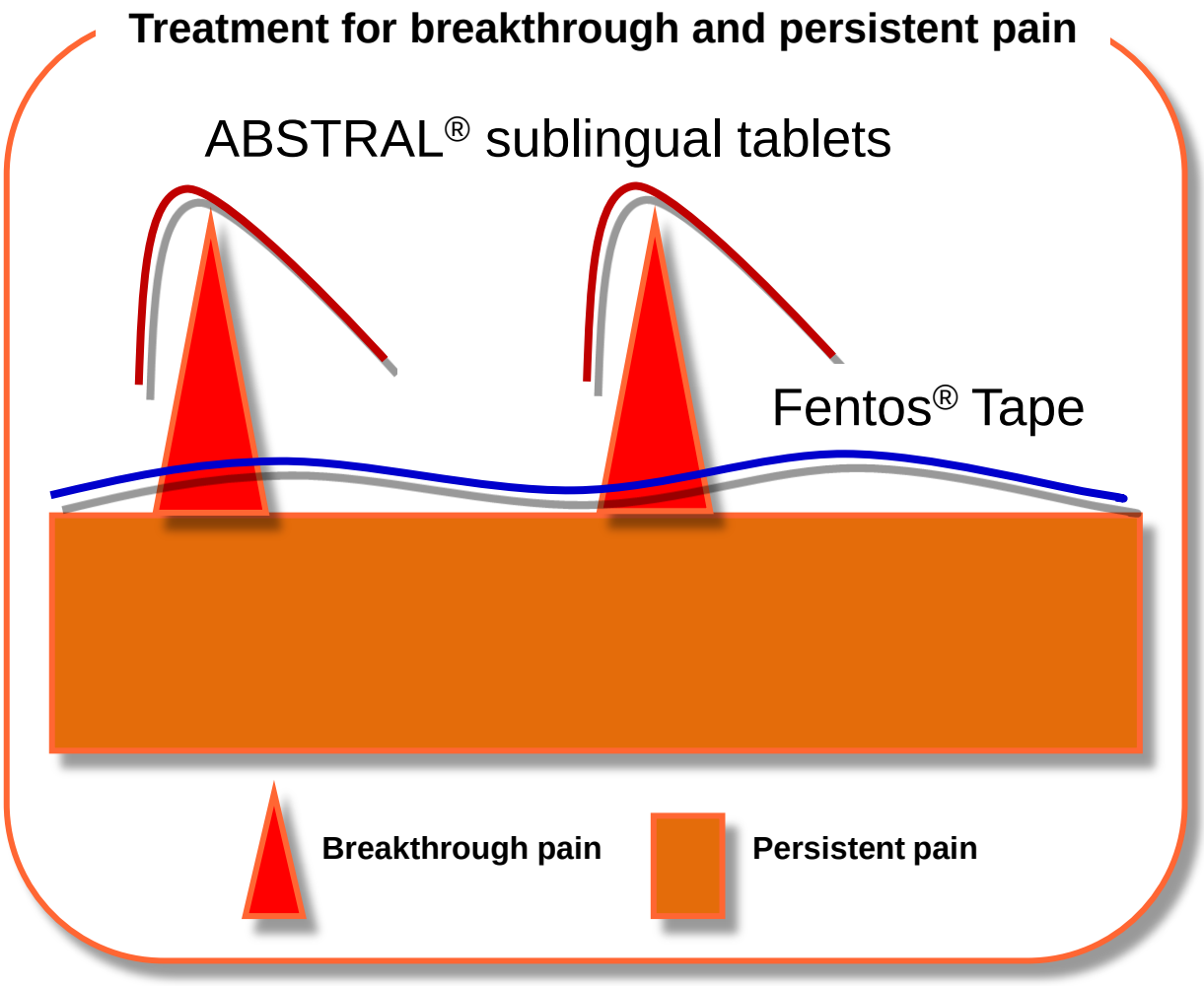
**2013: Forecast figures

Contribution to cancer pain treatment

KYOWA KIRIN

The approval of ABSTRAL® fentanyl formulation makes it possible to consistently control persistent and breakthrough cancer pain and contribute to pallitative cancer treatment.

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



ProStrakan: Update

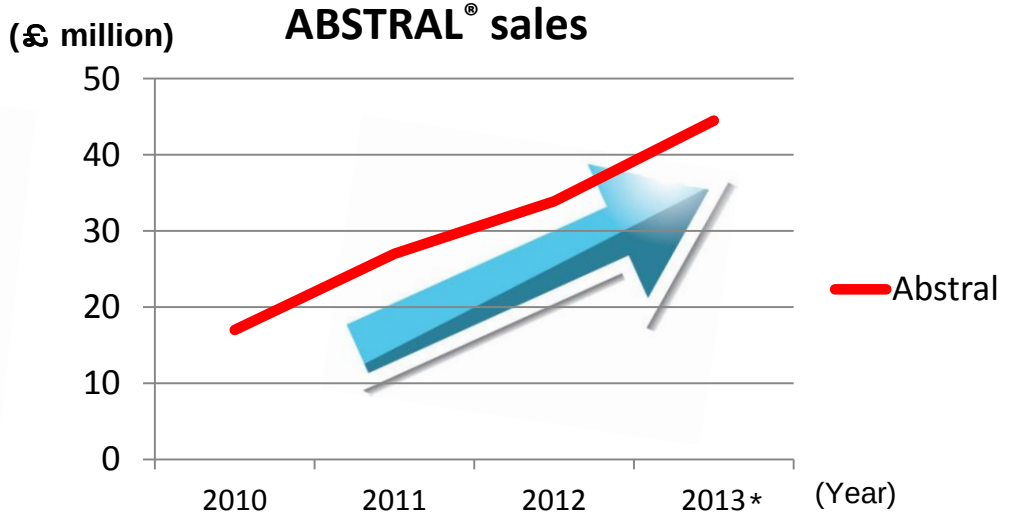
Strong growth in ABSTRAL® sales, SANCUSO® launched in Europe
Full year results from ProStrakan should make a positive contribution to consolidated Kyowa Hakko Kirin results

ABSTRAL®

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

SANCUSO®

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



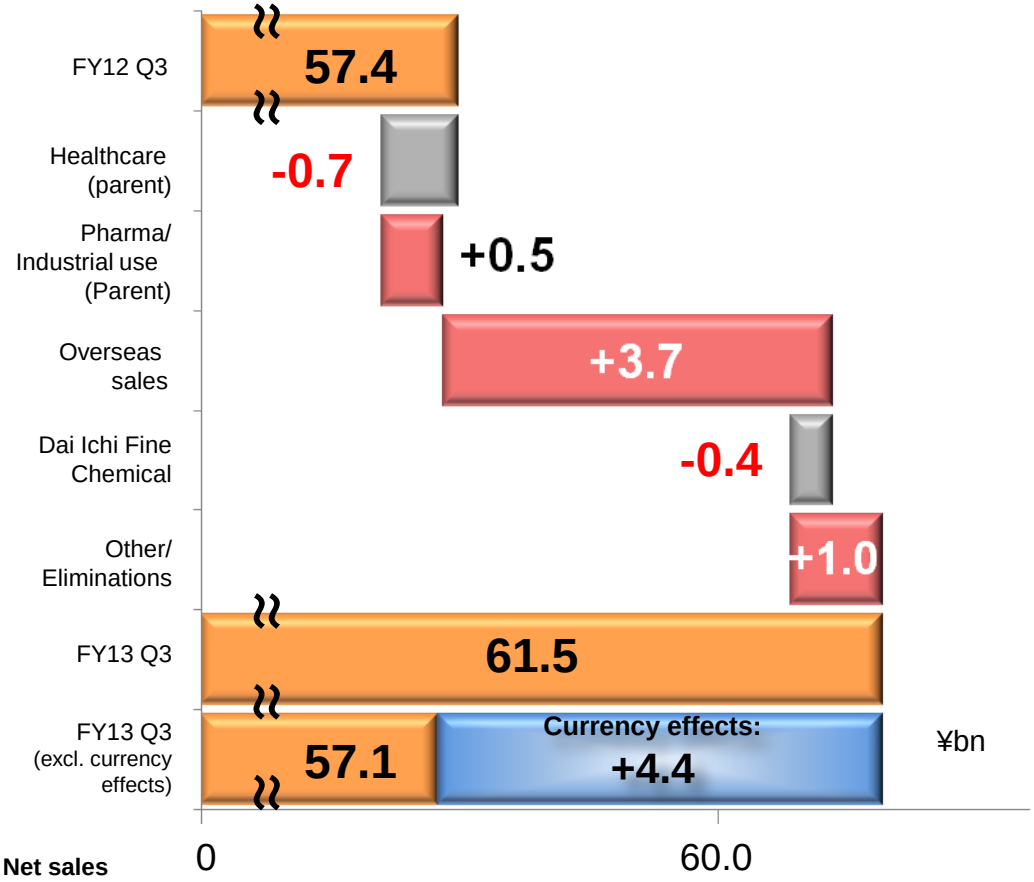
*2013: Forecast figures

Bio-Chemicals Business: Q3 results

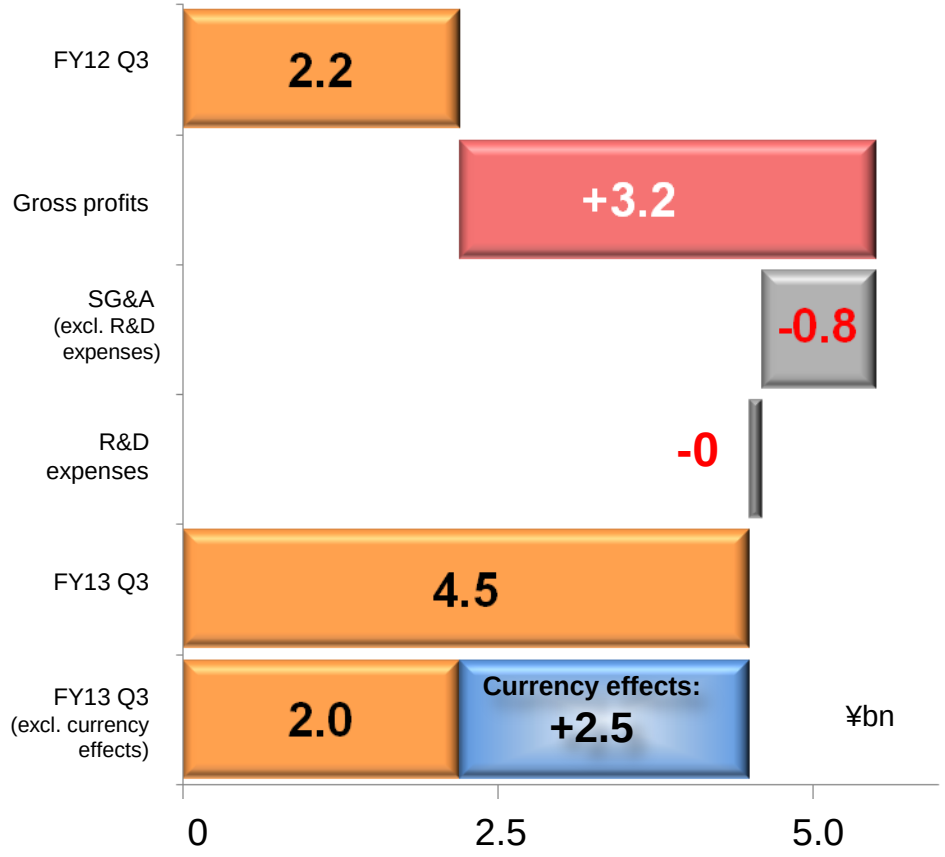
Bio-Chemicals Business: Q3 results: Analysis of YonY profit changes

KYOWA KIRIN

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

2013 Q3 Progress in development pipeline

KYOWA KIRIN

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)**

KRN23: Accelerating global development

KYOWA KIRIN

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.

ultragenyx pharmaceutical

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: Overview of development products

KYOWA KIRIN

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**

Overview of development of outlicensed antibodies and biosimilars

KYOWA KIRIN

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

Recent events on in-licensed pipelines

KYOWA KIRIN

ARQ 197

Promoting development of hepatocellular carcinoma in large Asian market

Target disease		Stage	Status
NSCLC	EGFR-Wild	Phase3	Discontinued
NSCLC	EGFR-Mut.	Phase2	On going
Gastric cancer		Phase2	On going
HCC		Phase1	On going

Remarks
Occurrence of interstitial lung disease in the study
EGFR-Mut. common among Asians
High frequency among Asian people, including Japanese
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
CKD	Type2 DM	Phase2	Suspended

Remarks
Revisiting development plan in 2013

(as of October 18, 2013)

Development progress with outlicensed compounds

KYOWA KIRIN

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

(as of October 18, 2013)

Currency effects

KYOWA KIRIN

Forex rates (period average)

	2012 Jan. – Sept.	2013 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