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# **FY December 2013 First Quarter**

**Reference documents for conference call**

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**Kyowa Hakko Kirin Co., Ltd.**

***Executive Managing Officer  
Kazuyoshi Tachibana***

*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.*

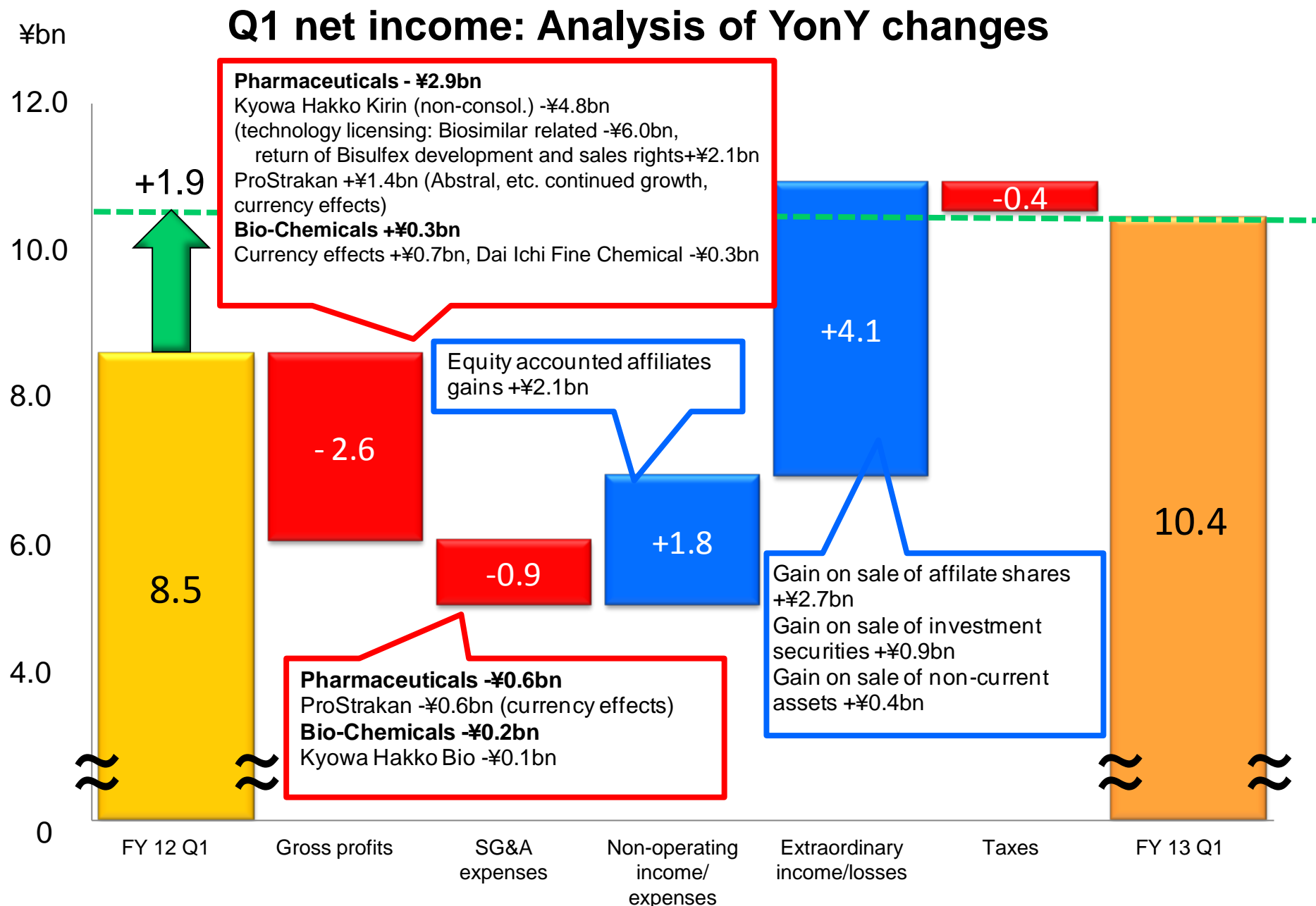
*This document contains information on pharmaceutical products (including products under development), but its contents should not be construed as promotion, advertising or as a medical recommendation.*

1. Summary of 1Q consolidated results
  2. Pharmaceuticals business
  3. Bio-Chemicals business
  4. Development Pipeline
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Summary of Q1 consolidated results:  
Analysis of YonY profit changes

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# Summary of Q1 consolidated results: Analysis of YonY profit changes



Summary of Pharmaceuticals business results Q1 results:  
Analysis of YonY profit changes

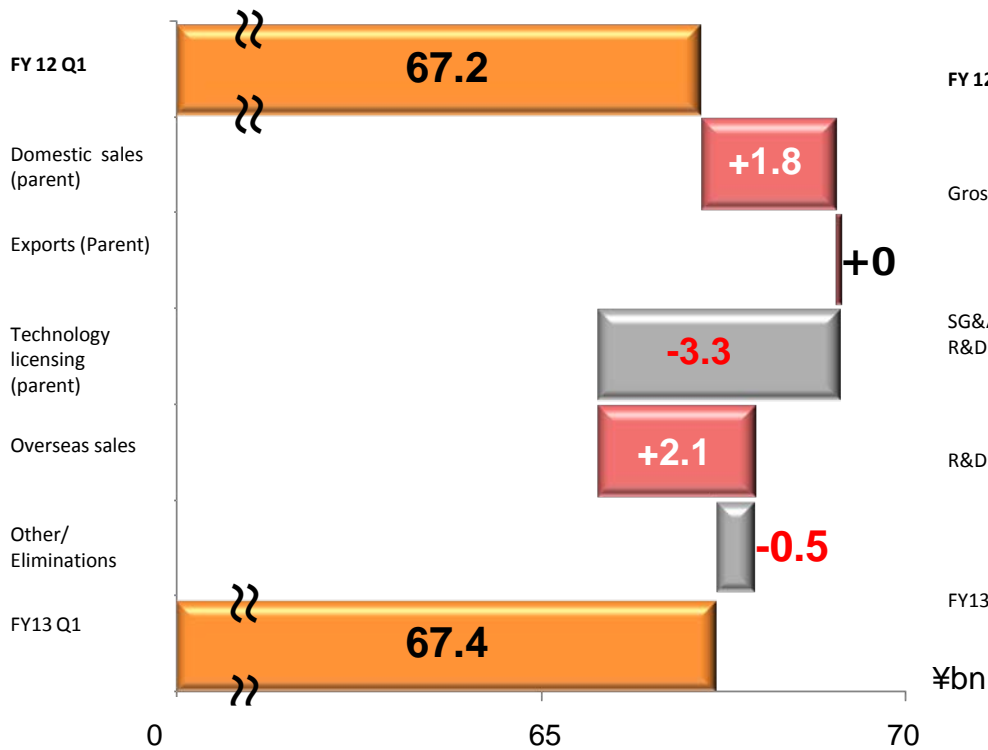
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# Pharmaceuticals business: Q1 results: Analysis of YonY profit changes

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(Consolidated)

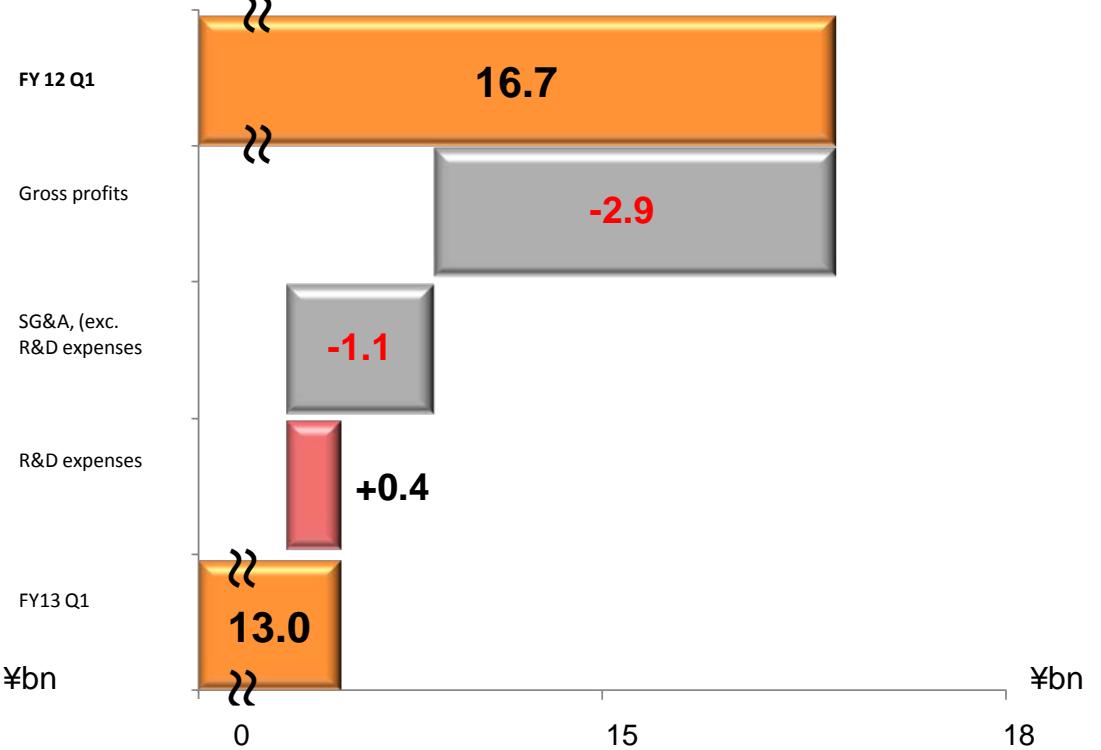
## Net sales



### Net sales

- Domestic pharmaceutical products (+¥1.8bn):
  - Products (shipments): PTN+3.9, ALK+0.8, REG+0.2, NSP-3.1, CONL-0.6, GRN-0.3
  - Nesp (NSP) : Sales declined due to pre-sales shipments last year of unified dosage product, reductions in NHI drug prices. Our share was maintained.
- Exports (+¥0.0bn): Currency effects approx. + ¥0.3bn
- Technology licensing (-¥3.3bn): Currency effects approx. +¥0.4bn
  - Biosimilar related (- ¥6.0bn) , return of development and sales rights for Bisulfex (+¥2.1bn), etc.
- Overseas sales (+¥2.1bn): Currency effects approx. +¥1.1bn
  - ProStrakan +¥1.4bn (forex +¥0.6bn), remainder Asia sales.

## Operating income



### Operating income

- Gross profits (-¥2.9bn):
  - Effects of NHI drug price cuts offset by volume growth and ProStrakan (PSK) growth but the large effect of the fall in licensing income from biosimilars led to lower profits
- SG&A (-¥1.1bn):
  - Mainly due to PSK currency effects. Also, sales rights amortization increases, etc.
- R&D expenses (+¥0.4bn)

# Sales of core domestic products: Analysis of YonY changes

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**Pharmaceutical sales affected by NHI drug price revisions and other factors, but core products performed well and in line with plan**

Unit: ¥ bn	2012 1Q (a)	2013 1Q(b)	(b) – (a)	Causes of changes
Nesp	13.8	10.6	-3.1	Reduction due to NHI price revisions and other factors Share in ESA market unchanged
Regpara	2.8	3.0	+0.2	Grew due to increasing market penetration
Allelock	9.9	10.7	+0.8	Grew due to high airborne pollen levels in 2013
Patanol	5.4	9.4	+3.9	Major increase due to high airborne pollen levels in 2013 and large number of patients with ocular symptoms
Gran	2.9	2.5	-0.3	Maintained high share but declined due to shrinking G-CSF market



## Summary of Bio-Chemicals business results Q1 results: Analysis of YonY profit changes

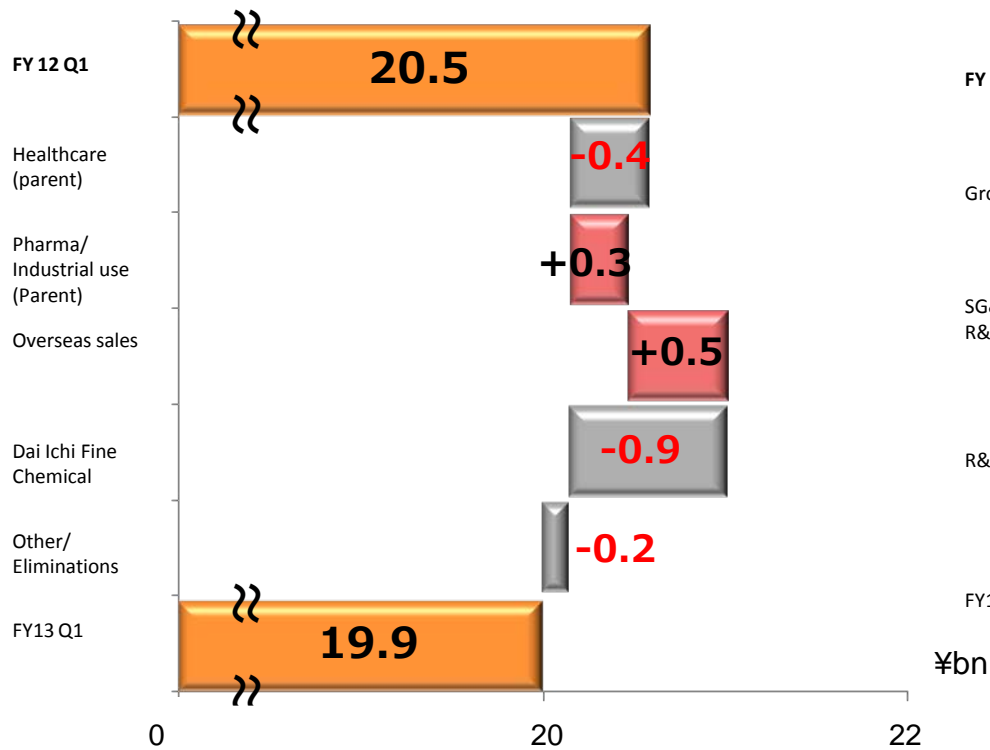
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# Bio-Chemicals business: Q1 results: Analysis of YonY profit changes

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(Consolidated)

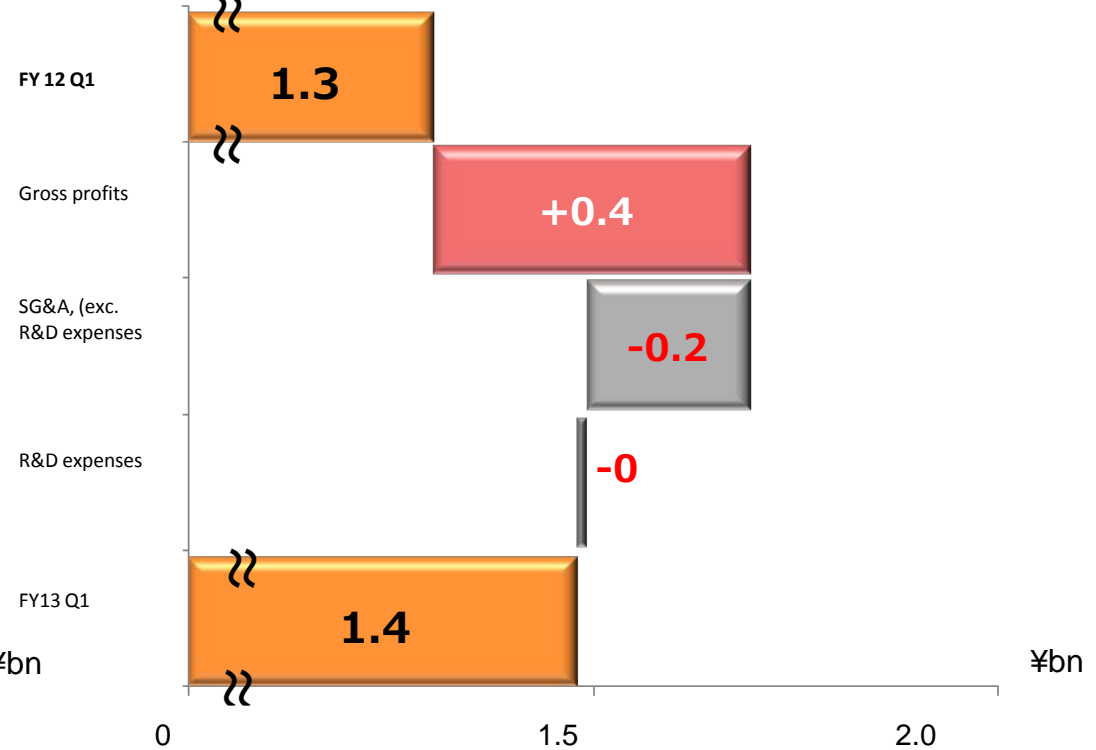
## Net sales



### Net sales

- Healthcare (-¥0.4bn): Mail order sales in line with 2012 Q1, raw materials/OEM sales of amino acids for beverages sluggish, etc.
- Pharma/ Industrial use (+¥0.3bn): Raw materials for generic pharmaceuticals strong, etc
- Overseas sales (+¥0.5bn): currency effects approx. +¥1.1bn
  - U.S.: Currency effects (+0.2), Other, some raw materials for supplements use were sluggish (-0.3)
  - Europe: Currency effects (+0.5)
  - Asia and others: Currency effects (+0.4), Other, some pharmaceutical raw materials were sluggish (-0.2)
- Dai Ichi Fine Chemical (-¥0.9): Transexamic acid results affected by concentration of shipments in Q1 last year (-0.5), Other, affected by business reorganization and exit from unprofitable products, etc. (-0.4)

## Operating income



### Operating income

- Gross profits (+¥0.4bn): Currency effects approx. +¥0.6bn
- SG&A(-¥0.2bn): Similar to last year

# Development pipeline

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## Approval for manufacturing and marketing of NOURIAST® (KW-6002), a novel anti-Parkinson's agent in Japan

- **Selective adenosine A<sub>2A</sub> receptor antagonist.**
- **First in Class anti-Parkinson's agent.**
- **Market size for anti-Parkinson's agents in Japan: ¥70bn (based on NHI price).**
- **NHI price to be listed in May 2013.**

## Approval for manufacturing and marketing of Onglyza®, to treat type 2 Diabetes in Japan (Otsuka, transferred rights to Kyowa Hakko Kirin)

- **Acts by selectively inhibiting dipeptidyl peptidase-4 (DPP-4) .**
- **The efficacy and safety of Onglyza® were confirmed in accordance with the guideline\*.**
- **Market size for DPP-4 inhibitors in Japan: ¥200bn (based on NIH price).**
- **NHI price to be listed in May 2013.**

## **KHK4563 (benralizumab )**

- **Anti-IL-5 receptor antibody.**
- **MedImmune is conducting a Phase 2b study in asthma worldwide except Asian countries.**
- **Kyowa Hakko Kirin is conducting a Phase 2a study in asthma in Japan and Korea.**

## **KRN951 (tivozanib)**

- **A highly selective inhibitor of VEGF receptor.**
- **AVEO-Astellas filed NDA for renal cell carcinoma in the US.**
- **Kyowa Hakko Kirin is conducting a Phase 1 study in Japan.**

## **FKB327**

- **Humira® (adalimumab) biosimilar.**
- **Final stage for preparation in initiating clinical study in first half of 2013.**

# Appendix

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## Forex rates

	1Q FY2012	1Q FY2013	change
<b>/ \$</b>	<b>¥79/\$</b>	<b>¥89/\$</b>	<b>+¥10/\$</b>
<b>/ €</b>	<b>¥104/€</b>	<b>¥118/€</b>	<b>+¥14/€</b>
<b>/ £</b>	<b>¥125/£</b>	<b>¥141/£</b>	<b>+¥16/£</b>

(Period average)

## Effects of foreign exchange

	Impact during 1Q /FY2013		
	Pharmaceuticals Business	Bio-Chemicals Business	Consolidated
<b>Net sales</b>	<b>+¥1.7bn</b>	<b>+¥1.0bn</b>	<b>+¥2.8bn</b>
<b>Operating income</b>	<b>+¥0.5bn</b>	<b>+¥0.6bn</b>	<b>+¥1.1bn</b>

Name	Partner	Phase			Application	Remarks
		I	II	III		
<b>Tivozanib (KRN951)</b>	<b>AVEO</b>				<b>FDA (Sep. 2012)</b>	<b>Cancer</b> (VEGF receptor inhibitor) (KRN951)
<b>KW-2871 (Low-fucose antibody)</b>	<b>Life Science</b>					<b>Cancer</b> (Anti-GD3 antibody) Low-fucose antibody
<b>MEDI-563 (KHK4563:POTELLIGENT®)</b>	<b>MedImmune</b>					<b>Asthma</b> (Anti-IL-5R antibody) KHK4563:POTELLIGENT®
<b>KRN5500</b>	<b>DARA</b>					<b>Peripheral neuropathy</b>
<b>LY2523355</b>	<b>Eli Lilly</b>					<b>Cancer</b> (Mitotic kinesin Eg5 inhibitor)
<b>RGI2001</b>	<b>REGiMMUNE</b>		<b>Phase1/2</b>			<b>Immunosuppressive</b>
<b>SAR252067</b>	<b>Sanofi</b>					<b>ulcerative colitis and Crohn's disease</b> (anti-LIGHT antibody)

(as of April 17, 2013)



# **KYOWA KIRIN**

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