



Interim Business Results for FY 03/2005

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Cautionary Statement Regarding Forward-looking Information

This material includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties.

Actual financial results may differ materially depending on a number of factors including adverse economic conditions, currency exchange rate fluctuations, adverse legislative and regulatory developments, delays in new product launches, pricing and product initiatives of competitors, the inability of the company to market existing and new products effectively, interruptions in production, infringements of the company's intellectual property rights and the adverse outcome of material litigation.

Consolidated Interim Business Results and Full-year Forecast for FY 03/2005

	Interim (billion yen)	YoY % change*	Full-year (billion yen)	YoY % change*
■ Net Sales	220.2	+4.6 %	440.0	+3.9 %
■ Operating income	55.4	+7.1 %	98.0	+0.9 %
■ Ordinary income	56.5	+9.9 %	99.5	+5.7 %
■ Net income	20.0	-35.3 %	35.5	-38.2 %

Note: Following the creation of Zepharma Inc. on October 1 (jointly with Fujisawa), the OTC drug business will be reported using the equity method in the second half of FY03/2005.

* YoY percent changes were calculated by deducting figures for the consumer business from the consolidated sales and incomes in the previous year.

Overview of Interim Business Results for FY 03/2005

Concentration of business resources on the ethical pharmaceuticals business

1. Sustained growth of mainstay products
2. Smooth progress of the global development of Vesicare
 - Launch in Europe (in August) and NDA submission in Japan (in August)
3. Business development in the US – start of marketing activities
 - Copromotion of Flomax (started in October)
 - Copromotion of GSK's VALTREX (started in August)
 - Acceleration of preparation for launch of Vesicare
4. Further consolidation of infrastructure for generating profits
 - Divestiture of consumer businesses (completed in June)
 - Separation of the OTC drug business
 - ⇒ Creation of Zepharmia Inc. (jointly with Fujisawa) (in October)
5. Preparations for merger with Fujisawa

Continued Growth of Mainstay Products' Sales

(billion yen)

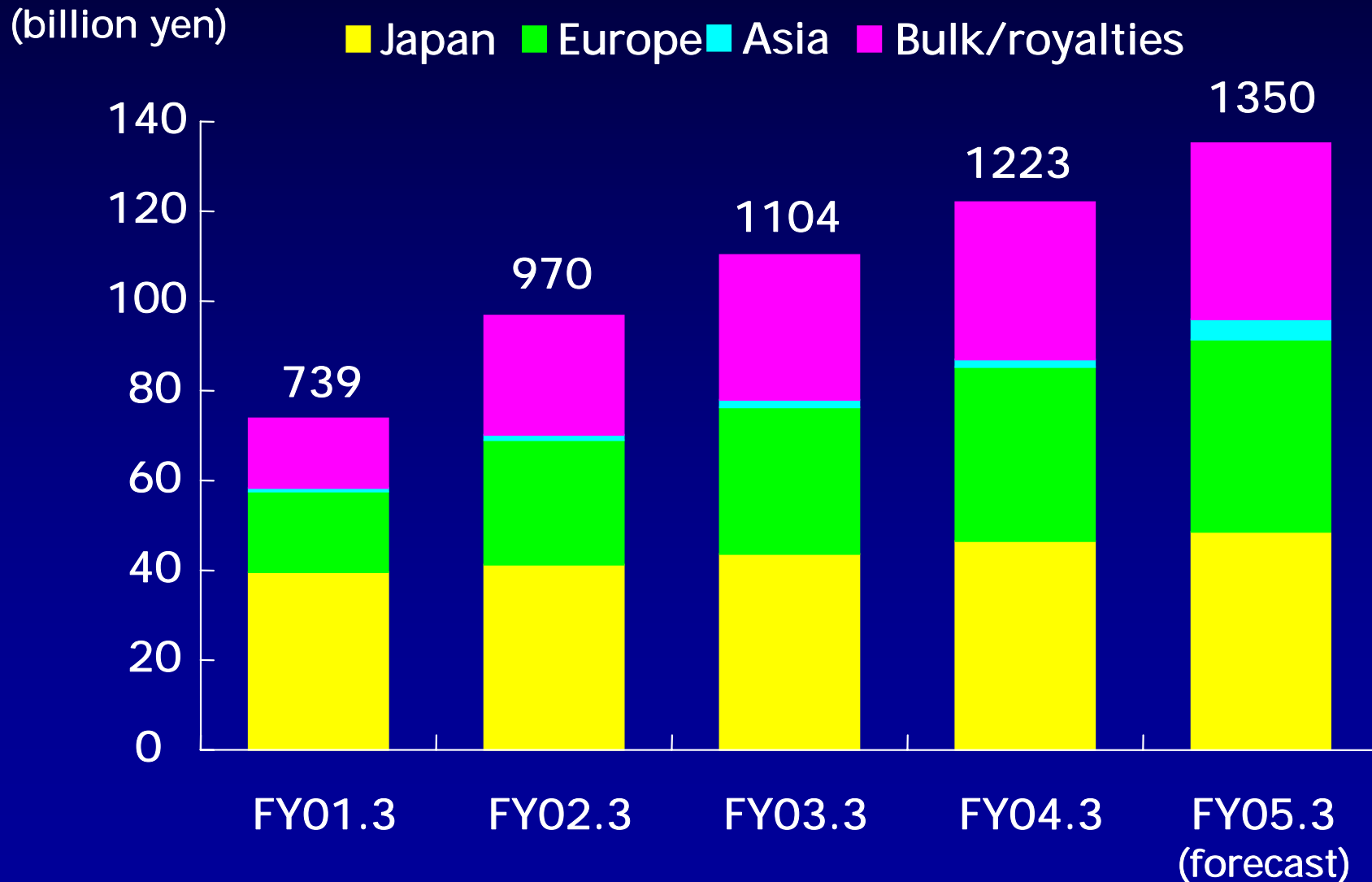
	Interim result (YoY change)	Full-year forecast (YoY change)
Consolidated sales	2,202 (+97)*	4,400 (+167)*
Harnal (domestic + overseas)	681 (+95)	1,350 (+126)
Lipitor	416 (+36)	860 (+83)
Micardis	107 (+80)	240 (+153)
Gaster (domestic Rx)	364 (-17)	710 (-43)

Note: Consolidated full-year sales forecast includes sales of the OTC drug business in the first half of the fiscal year, but not in the second half, because this business was transferred to Zepharmia Inc., jointly created with Fujisawa Pharmaceutical Co., Ltd., on October 1.

* YoY changes were calculated by deducting figures for the consumer business from the consolidated sales and incomes in the previous fiscal year.

Harnal

– Sustained growth on a global basis –



Vesicare (YM905)

- Smooth progress of the global development -

Europe

- Lunched in Aug. 2004
- Marketed in 7 countries (including the UK and Germany) at present
- Launching expected subsequently in 10 other countries where approval has already been received

US

- 1st quarter: submission of additional clinical pharmacology data to the FDA
- Expected launching in Dec. 2004 or Jan. 2005

Japan

- NDA submitted in Aug. 2004

Vesicare

- Launching in Europe –

Outstanding Profile

- Efficacious in all symptoms of OAB*: Urgency, Frequency, Urge Incontinence and Nocturia
- Low incidence of dry mouth
- Excellent persistency on therapy with long term use

* OAB: Overactive bladder



Welcome to the new world of Overactive Bladder relief



Vesicare® is effective in all the symptoms of OAB including nocturia¹
 Vesicare reduces Urgency episodes by over 50% after 12 weeks^{2*}
 Over 60% of patients were totally dry after 1 year on Vesicare³
 89% of patients on Vesicare do not experience dry mouth^{3,4}



Rapid results, enduring success



ABBREVIATED PRODUCT INFORMATION

Vesicare® 5 and 10 mg, film-coated tablet
Composition: each Vesicare 5 or 10 mg film-coated tablet contains 5 or 10 mg solifenacin succinate. **Indications:** symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome. **Dosology:** 5 mg solifenacin succinate once daily if needed, the dose may be increased to 10 mg solifenacin succinate. **Contraindications:** urinary retention, severe gastro-intestinal condition (including toxic

megacolon), myasthenia gravis or narrow-angle glaucoma. Hypersensitivity to the active substance or to any of the excipients. Patients undergoing haemodialysis, with severe hepatic impairment, with severe renal impairment or moderate hepatic impairment and who are on treatment with a potent CYP3A4 inhibitor, e.g. ketoconazole. **Special warnings and special precautions for use:** Vesicare should be used with caution in patients with severe renal impairment, moderate hepatic impairment, and doses should not exceed 5 mg

for these patients, clinically significant bladder outflow obstruction at risk of urinary retention, gastrointestinal obstructive disorders, risk of decreased gastrointestinal motility, concomitant use of a potent CYP3A4 inhibitor, hiatus hernia/gastro-oesophageal reflux and/or who are concurrently taking medicinal products (such as bisphosphonates) that can cause or exacerbate oesophagitis, autonomic neuropathy. The maximum effect of Vesicare can be determined after 4 weeks at the earliest.

interaction with other medicinal products and other forms of interaction: solifenacin can reduce the effect of medicinal products that stimulate the motility of the gastro-intestinal tract, such as metoclopramide and itopride. In vitro studies have demonstrated that solifenacin does not inhibit CYP1A2, 2C9, 2C19, 2D6, or 3A4 derived from human liver microsomes. Solifenacin is metabolised by CYP3A4. The maximum dose of Vesicare should be restricted to 5 mg, when used simultaneously with ketoconazole or therapeutic

doses of other potent CYP3A4 inhibitors. **Undesirable effects:** due to the pharmacological effect of solifenacin, Vesicare may cause anticholinergic undesirable effects of (in general) mild or moderate severity. The frequency of anticholinergic undesirable effects is dose related. The most commonly reported adverse reaction with Vesicare was dry mouth. The severity of dry mouth was generally mild and did only occasionally lead to discontinuation of treatment. **Marketing authorisation number(s):**

RVG 29151/2 Date of first authorisation: 16 December 2003, updated 8 June 2004
General classification for supply: medicinal product subject to medical prescription. For more information, see registered SPC. Yamanouchi Europe B.V., P.O. Box 108, 2250 AC Leidschendam, The Netherlands.
References:
 1 Vesicare Smpc. 2 Data on File, Study 019
 3 Data on File, Study 015. 4 Data on File, Study 018

*% of patients on Vesicare were totally dry at 12 weeks

Business development in the US

- Start of marketing activities -

Yamanouchi MRs: 135 for urologists and 200 for PCP

Specialist

PCP

Launch/start
of promotion*

Flomax
(tamsulosin)

BIPI
Yamanouchi

BIPI
Yamanouchi

Oct. 2004

Vesicare
(solifenacin)

Yamanouchi

GSK and partly
Yamanouchi

Dec. 2004 –
Jan. 2005

VALTREX -GSK

Yamanouchi
(partly)

-

Aug. 2004

* Including expectations

In preparation for the launching of Astellas Pharma



Sustained growth in Japan and overseas
Further consolidation of the business platform

