Business Results for FY2006

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Overview of FY2006

1. Announced VISION2015 and MTP2010
2. Expanded Rx business in Japan and overseas
   Prograf: continued growth, Vesicare: sharp increase
3. Launched new products
   Vesicare in Japan, Vaprisol in the US
4. Strengthend the R&D pipeline
   Progress in in-house projects (YM150, YM155, YM178 etc.)
   Proactive in-licensing (YM311/FG-4592, ILY-101, telavancin (Japan))
   Platform to antibody drugs (CD40 antagonistic mAb, alliance with Regeneron)
5. Improved cost structure
6. Reinforced corporate governance
7. Improved capital efficiency
   (dividend increase / share buyback / treasury stock cancellation)

Financial Results of FY2006 (1)

(billion yen)

	Results			FY2006 forecasts	Remarks
	FY2005	FY2006	Changes		
Net sales	879.3	920.6	+41.2	918.0	Impact of - exchange fluctuations: +26.0 - NHI drug price revision: -21.2 - non-Rx business divestiture: -27.9 (ref.) Impact of extra shipment in FY04 on FY05 results: 11.9
Cost of goods ratio to sales	272.9 31.0%	284.0 30.9%	+11.0 - 0.1ppt		Slightly improved (Product mix improved)
SG&A (excl. R&D) ratio to sales	271.2 30.8%	278.1 30.2%	+6.8 - 0.6ppt		- Increase due to exchange fluctuations - Increase in personnel expenses overseas
R&D ratio to sales	142.0 16.2%	167.9 18.2%	+25.8 +2.0ppt	172.0	Including upfront fees for alliance with - FibroGen: 37.5 - Regeneron: 9.6
Operating income ratio to sales	193.0 22.0%	190.5 20.7%	-25 -1.3ppt	180.0	Impact of exchange fluctuations: +8.4

YEN/1USD (average rate)	113	117	+4	115
YEN/1Euro (average rate)	138	150	+12	145

Financial Results of FY2006 (2)

(billion yen)

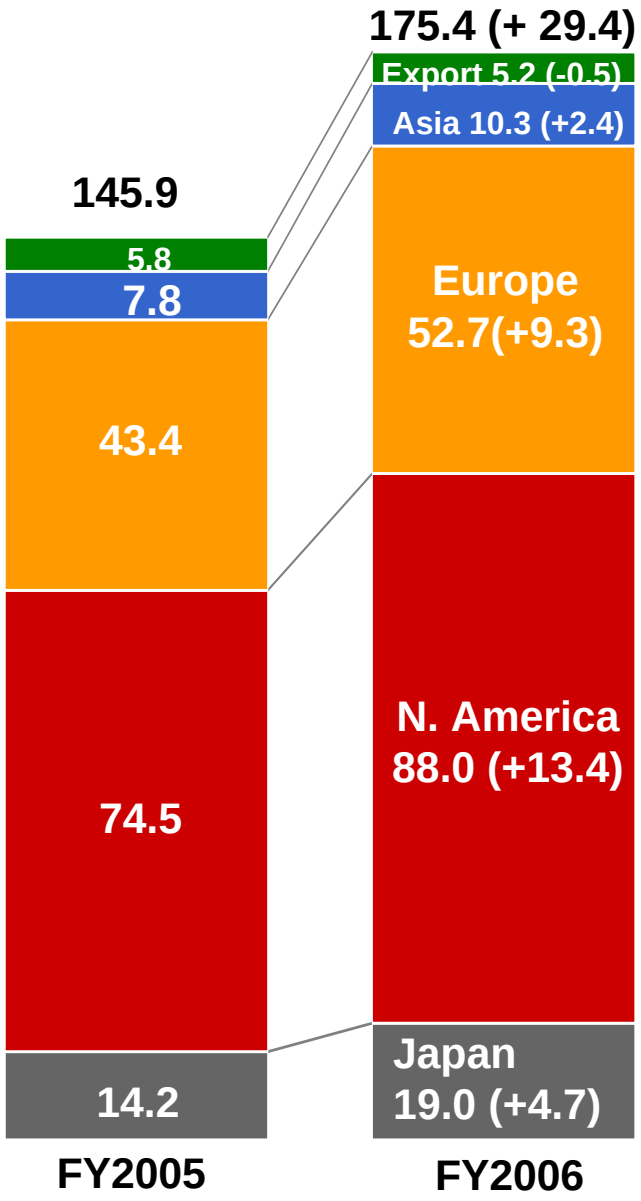
	Results			FY2006 forecasts	Remarks
	FY2005	FY2006	Changes		
Operating income	193.0	190.5	- 2.5	180.0	
Net non-operating incomes / expenses	9.5	7.2	- 2.2		- Increase in interest and dividend income - Exchange losses in Europe
Ordinary income	202.5	197.8	- 4.7	186.0	
Extraordinary gains	7.8	41.0	+33.1		Gains from - divestiture of Zepharma : 21.2 - sale of investment securities: 12.3
Extraordinary losses	33.4	27.1	- 6.2		Losses from - integration and closure of business bases: 17.6 - loss on impairment: 6.0 - special retirement benefits: 1.2 In FY2005, business integration expenses booked
Net income	103.6	131.2	27.6	119.0	

EPS (YEN)	183.88	244.07	+60.19	219.01
ROE (%)	8.8	11.3	+2.5ppt	
Dividend per share (YEN)	70	80	+10	
DOE* (%)	3.3	3.7	+0.4ppt	

*DOE=ROE x payout ratio

Prograf: Continued Growth in Global Market

Sales (billion yen)



Japan

- Sales from transplant indication: steadily increasing
- Sales from RA indication:
  - Over half of the sales growth from RA indication
- Additional indication for lupus nephritis (Jan. 2007)

North America

- Rx share in the US primary immunosuppressant* market for newly transplanted patients
  Liver: 91%, Kidney: 81%, Heart: 59% (CY2006)
- TRx share in the US primary immunosuppressant* market: 58.9% (March 2007)

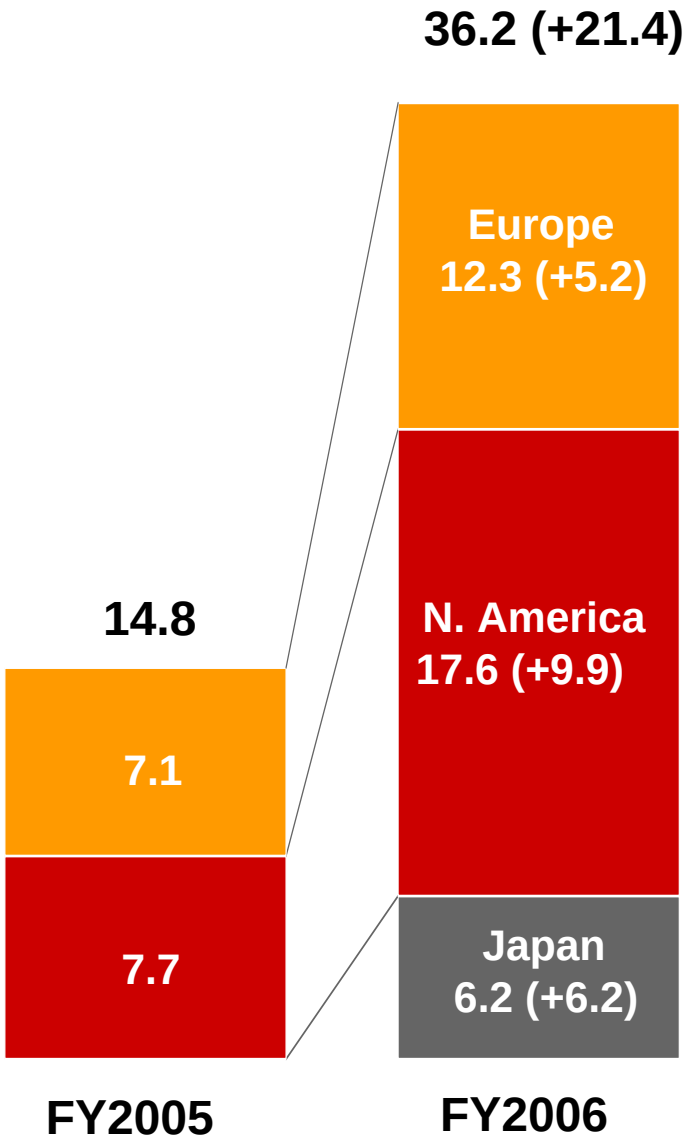
Europe

- Sales share in the primary immunosuppressant* market: 49.9% (February 2007)
- Sales share in the total immunosuppressant market: 26.9% (February 2007)

*Primary immunosuppressant: calcineurin inhibitor (CNI)

Vesicare: Robust Sales Increase

Sales (billion yen)



Japan

- OAB market: 10.5% growth*
- Vesicare sales: ¥6.4 billion*
- Market share: 19%* (FY2006, 2nd largest)

*NHI drug price basis

North America

- OAB market in the US continually expanding
- Recent weekly Rx share in the US (NRx:12.4%, TRx:11.3%)
- Listing on formulary of managed care organizations increasing

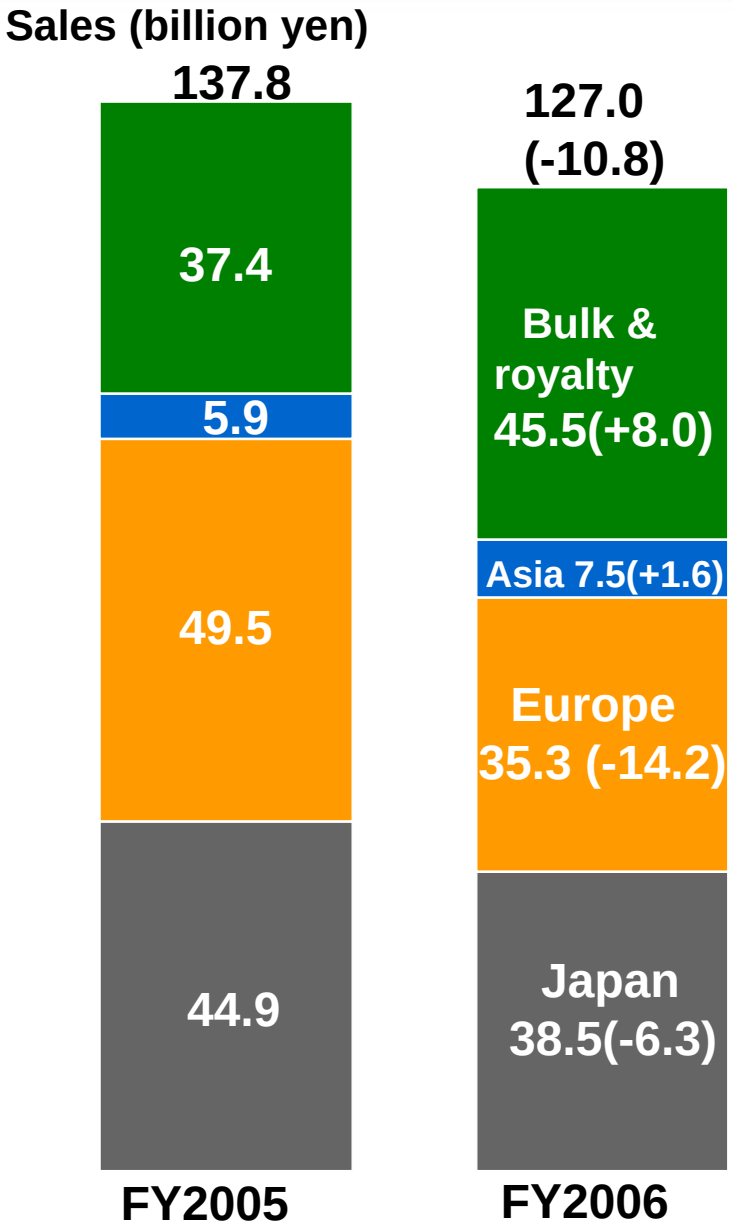
Europe

- Sales share: 21.1% (Feb. 2007, 2nd largest)
- Only Vesicare showed growth in OAB market

Asia

- Launched in the Philippines, Thailand, Taiwan, Indonesia and Hong Kong

Harnal



Japan

- ■17% down after the adjustment of the impact of extra shipment on FY2005 sales
  - Impact of NHI drug price revision: -13.4%,
  - Volume decrease: -3.6%
- ■Sales share: 49.7% (-5.6%)
- ■Year-on-year increase on a volume basis after Sep. 2006
- ■Estimated generic share: 9% (volume basis)

Europe

- ■Capsule formulation sales: above budget
- ■TOCAS sales: accounting for 46% of total Omnic/TOCAS
- ■Growth in Russia

Bulk & royalty

- ■Sales in the US: $365MM (1Q/CY2007, +53%)
- ■TRx share: 49% (March 2007 MAT, +25%)

- Co-promotion revenue from Boehringer Ingelheim significantly increased thanks to robust sales in the US

Sales in Japan

(billion yen)

	FY2005	FY2006	Chgs.	FY2006 forecasts	Remarks
Total Rx sales in Japan	440.4	455.2	+14.8	459.1	Extra shipment adjusted**: +2.9
Lipitor	91.5	94.7	+3.1	95.3	Market share*: 40.6%(+1.9%) Sales (NHI drug price basis): +1.5% Extra shipment adjusted**: +0.2%
Gaster	68.8	62.2	-6.5	63.2	Estimated market share of generic products: 9% Sales (NHI drug price basis): -10.9% Extra shipment adjusted**: -12.1%
Micardis	37.3	50.3	+13.0	50.0	Market share*: 13.1% (+2.2%) Extra shipment adjusted**: +28.0%
Myslee	17.1	19.4	+2.2	19.7	Market share*: 30.8% (+3.2%)
Seroquel	15.2	16.8	+1.5	16.4	Market share*: 15.8%(flat)
Cefzon	18.4	14.7	-3.6	15.3	
Funguard	14.0	12.8	-1.2	12.8	Market share*: 49.2% (-0.9%) Competition with other oral formulation drugs
Vaccine	14.1	13.3	-0.7	15.1	

* Market share on a NHI drug price basis.

**Extra shipment adjusted: After adjustment of the negative impact on FY2005 sales due to extra shipment in the end of FY2004 before the merger

Sales by Geographic Regions

(billion yen)

	FY2005	FY2006	Changes	Remarks
Consolidated	879.3	920.6	+41.2	
Japan	511.1	501.6	-9.4	Rx business: +14.8 Non-Rx business divestiture: -27.9 Export sales: +1.5
North America	145.3	173.5	+28.2	Prograf +13.4, VESIcare +9.9, Mycamine +2.3, Amevive +2.4, Adenoscan +1.7
Europe	203.2	219.6	+16.4	Prograf +9.3, Vesicare +5.2, Harnal -14.2 Harnal bulk & royalty +8.0, Eligard +3.2 Others +5.7
Asia	19.6	25.7	+6.0	Prograf +2.4, Harnal +1.6

Operating Income by Geographic Regions

(billion yen)

	FY2005	FY2006	Changes	Remarks
Consolidated	193.0	190.5	- 2.5	
Japan	138.1	116.6	- 21.5	Increase in R&D expenses Decrease in SG&A expenses
North America	32.7	51.5	+18.8	Increase in gross profit
Europe	18.3	23.7	+5.3	Increase in gross profit Increase in SG&A expenses
Asia	3.8	3.7	- 0.0	
Eliminations	- 0.0	- 5.2	- 5.1	

Profit of "Urology / Vaprisol business" in North America in FY2006 :over ¥1.0 billion (on a direct expenses basis)

Full Year Forecasts for FY2007

(billion yen)

	FY2006	FY2007 forecasts	Changes
Net sales	920.6	968.0	+47.3
R&D expenses	167.9	141.0	-26.9
Operating income	190.5	250.0	+59.4
Ordinary income	197.8	260.0	+62.1
Net income	131.2	152.0	+20.7
EPS (YEN)	244.07	295.51	+51.44
YEN/USD (average rate)	117	115	
YEN/Euro (average rate)	150	150	

Pipeline Overview

Status of R&D Pipeline

Progress since announcement on 3Q/FY2006 results

■ **Approved:**

- Vaprisol(YM087): Hypervolemic hyponatremia (US) February 2007
- Advagraf(FK506 modified release):
  Suppression of organ rejection in organ transplant (Europe) April 2007

■ **Filed:**

- YM177: Low back pain, shoulder periarthritis, cervico-omo-brachial syndrome and tenosynovitis (Japan) February 2007
- YM1170: Non-erosive reflux disease (Japan) February 2007
- FK506: use of Prograf and MMF as an adjunct therapy for the prophylaxis of organ rejection in kidney transplantation (US)
  *Received approvable letter from the FDA in March 2007 (sNDA filing: February 2006)
- telavancin: Complicated skin and soft tissue infections (Europe) April 2007
- CVT-3146: Pharmacologic stress agent in cardiac perfusion imaging studies (US) May 2007

■ **Entered Phase-2:**

- YM150: Prophylaxis of thromboembolic complications associated with AF (Japan)
- ASP2151: Herpes zoster and genital herpes (Japan)
- ASP8825(XP13512): Restless legs syndrome and painful diabetic neuropathy (Japan)

Development Status of FK506MR in Europe and Japan

- **Europe:**
  - **Status:** Received a positive CHMP opinion in February 2007
    Received an approval from the European Commission in April 2007
  - **Brand name:** Advagraf
  - **Indications:** Prophylaxis of transplant rejection in adult kidney or liver allograft recipients
    Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients
  - **Launch date:** UK and Germany in June (scheduled)
    Other countries will follow.

- **Japan:**
  - **Status:** Filed in May 2006

Development Status of FK506MR in the US

- Received an action letter from the FDA in January 2007

  - Kidney and liver transplant : approvable, Heart transplant : not approvable

<Liver transplant >

- Issues raised by the FDA: - To submit additional clinical data for FK506MR
- Astellas response: - Based on the discussion with the FDA, Astellas will submit additional clinical data to the FDA.
  - Submission is planned in 2007/3Q (calendar year).
  - FDA's review period is estimated for approximately six months after the submission of the data.

<Kidney transplant>

- Issues raised by the FDA: - To submit additional clinical data for FK506MR.
  - To submit additional clinical data for combination use of FK506MR with another immunosuppressant
- Astellas response: - We plan to start the discussion with the FDA soon.

<Heart transplant>

- Issues raised by the FDA: - To submit additional clinical data for FK506MR
- Astellas response: - We have not yet started discussions with the FDA.
  - Next actions to be taken are under internal discussion.

Development Status of FK463

■Status in the US:

➢sNDA for candidemia and other *candida* infections:
Submitted in December 2006

➢sNDA for dosage of 300mg alternate-day administration for esophageal cadidasis:
Submitted in February 2006

- An approvable letter received from the FDA in December 2006
- Next actions under discussion/preparation
(Efficacy was confirmed. However, further safety evaluation of the new dosage was required.)

■ Status in Europe:

➢Deep-seated fungal infections: Submitted in April 2006

- An additional non-clinical study required by the EMEA.
- We will respond to the EMEA after completing this study, which is currently ongoing.

Development Status of Main Projects

YM150 **(Oral Factor Xa inhibitor)**	**Prevention of VTE after major orthopedic surgery** **Prophylaxis of thromboembolic complications associated with AF**	**VTE:** **Europe: P-2b study (for THR*) ongoing (enrollment completed)** **US: Preparation for P-2 study (for TKR*)** **Japan: P-2 (an international trial in Japan/Asia)** **AF:** **US/Europe: P-2** **Japan:P-2 study initiated (an international trial in Japan/Asia/Oceania)**
YM178 **(β3 receptor agonist)**	**Urinary frequency, urinary incontinence or urgency associated OAB**	**Europe: P-2b study ongoing (enrollment completed)** **Japan: P-1 study completed**
YM155 **(Survivin suppressant)**	**Non-Hodgkin's lymphoma (NHL)** **Hormone Refractory Prostate Cancer (HRPC), Non Small Cell Lung Cancer (NSCLC),** **Metastatic Melanoma (MM)**	**NHL: Preparation for P-2 study** **HRPC, NSCLC, MM:** **US/Europe: Enrollment completed in P-2 monotherapy trials (under data analysis)** **Japan: P-1 monotherapy trials completed**

P-2 results in the US/Europe and P-1 results in Japan will be presented at ASCO in June 2007

*THR: Total Hip Replacement, TKR: Total Knee Replacement

FG-2216/YM311 Status Update

- All clinical trials* of FG-2216/YM-311 and FG-4592 are now on clinical hold by instruction of US FDA
  - This FDA action follows a serious adverse event (SAE), which occurred in a FG-2216 P2b clinical trial of pre-dialysis CKD anemia: a case of fulminant hepatitis resulting in death
  - Astellas and FibroGen are investigating this SAE; definitive cause not yet determined
  - FG-2216 and FG-4592 have similar mechanisms of action but are chemically distinct
  - FDA has instructed FibroGen to immediately stop dosing all subjects in clinical studies with either compound.

*FG-2216 : P2b pre-dialysis CKD (US), P2 MDS(**) (US)
FG-4592: P2a pre-dialysis CKD (US)
**MDS: myelodysplastic syndrome

- Astellas and FibroGen are collaborating to address FDA questions