



- Heading toward the Real Growth -

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 **SHIONOGI & CO., LTD.**

The 1st Medium-Term Business Plan (April 2000—March 2005)

**Concentration on the
prescription drug business**

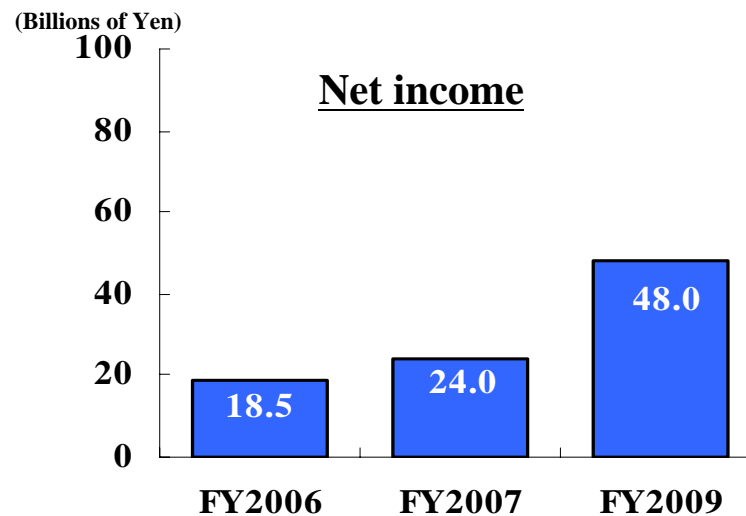
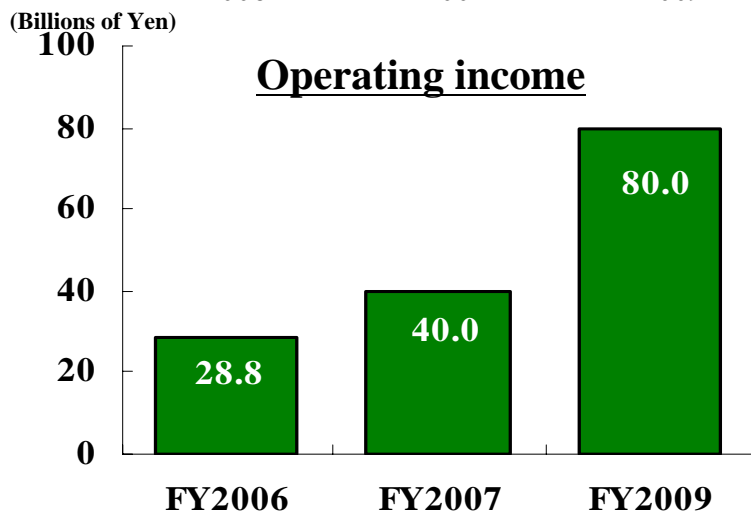
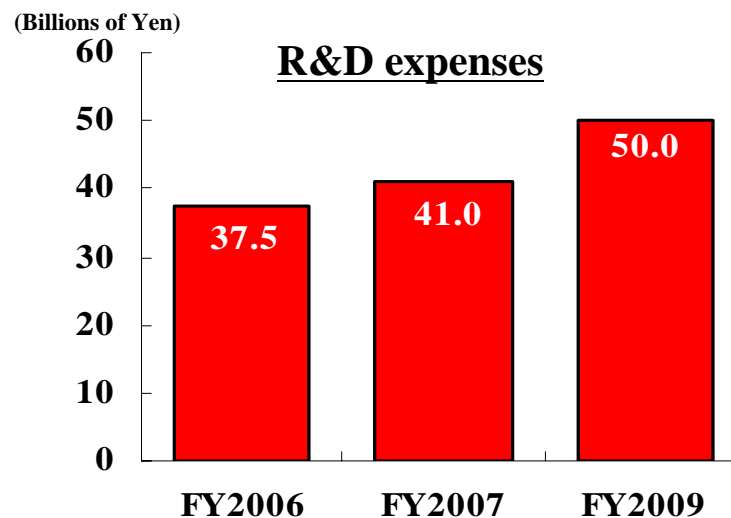
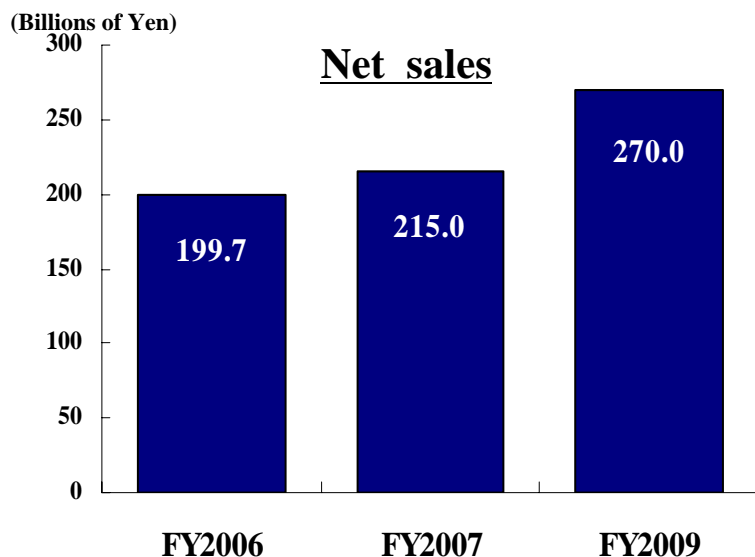
The 2nd Medium-Term Business Plan

(April 2005—March 2010)

**Entering a stage to accelerate
toward significant growth**

- ◆ **Full contribution of Crestor[®]
(royalty income and domestic sales)**
- ◆ **Activating R&D activities**
- ◆ **Launching new products in
domestic market
(10 products in total)**

Consolidated Financial Targets for the 2nd Medium-Term Business Plan



Performance Summary 1Q-3Q and forecasts for FY2007



(Billion Yen)

	FY2007 1Q-3Q	Y on Y change(%)	FY2007 forecasts	Y on Y change(%)
Net Sales	162.4	+8.7%	215	+7.6%
Operating Income	29.6	+39.3%	40	+38.6%
Ordinary Income	29.5	+38.7%	40	+42.3%
Net Income	18.6	+47.3%	24	+29.1%
R&D Cost	30.7	+11.1%	41	+9.5%

Research and Development

- ◆ **Smooth Progress on Development Activities**
 - **Both Globally and Domestically**
 - **Launch Claritin[®] DS/Pediatric Indication**
 - **NDA Submission of Duloxetine (M.D.)**
 - **Completion of Enrollment of S-2367 Phase IIb on time**
 - **Initiation of 2 Phase IIa (S-777469/Peramivir)**
- ◆ **Initiated Phase I Studies for 4 New Products**
(3 in-house compounds)

Licensed-out Products

◆ **Crestor[®]**

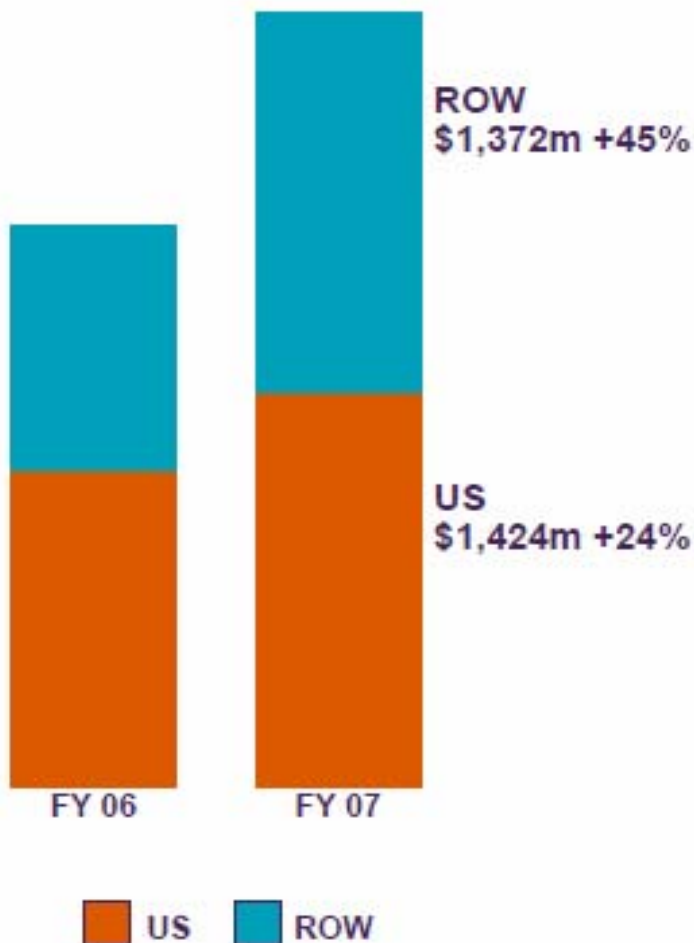
- **Continuous Growth Globally by AstraZeneca**
- **US New Indication → Future Growth to be expected**

◆ **Doripenem (Doribax[®])**

- **Johnson & Johnson obtained US Approval (October, 2007)
-cIAI and cUTI**
- **Shionogi began supplying final formulation**



FY 07 Sales: \$2,796m +33%



Sales growth rates at CER

- **ROW**
 - Western Europe +26%
 - Canada +43%
 - Japan launch: 8.8% share*

- **US**
 - US statin TRx's +8%
 - Crestor™ TRx's +22%**
 - Crestor™ TRx's share 8.6%**

- **US Atherosclerosis indication launched in Nov 07**

Source: * IMS Health
 ** IMS Health, US NPA December 2007

Domestic Sales

◆ New Products Began to Contribute

Ethical Drug (Domestic Sales)	
FY2007	Y on Y change(%)
1Q (Apr.-Jun.)	-0.1%
2Q (Jul.-Sep.)	+2.4%
3Q (Oct.-Dec.)	+2.6%
1Q-3Q Total	+1.7%

◆ Crestor[®] : Growing

Oct. – Dec. 2006 : Less than 0.1 bil. yen/month
 (more than 10 times)

Oct. – Dec. 2007 : 1.2 bil. yen/month



Pipeline



 **SHIONOGI & CO., LTD.**

Development status and launch schedule for new drugs



	DCS	Ph1/Ph2a	Ph2b	Ph3	Files	Launch	
Targeted R&D Areas	Infectious Diseases	S-349572/S-265744/S-247303 (HIV infection)	S-013420 (Bacterial infection)	Finibax® (Pediatric infection)	Doripenem (J&J, Bacterial infection)	Doripenem (J&J, Bacterial infection*)	
		S-021812(Peramivir) (Influenza)				Finibax® kit product (FY2006)	
	Pain	★★	Final review stage for in-licensing (Non-cancer pain treatment)		Duloxetine (DNP)	OxiNorm® (FY2006)	
	MS		Final review stage for in-licensing (Insulin sensitizer)	S-2367 (Anti-obesity)		Irbesartan (Hypertension)	→ (FY2008)
		Final review stage for in-licensing (Lipid lowering agent)					
Frontier Areas	Allergy	★	S-777469 (Pruritus resulting from AD)			Claritin® dry syrup (FY2007)	
			S-555739 (Allergic disease)				
	Others	★	S-888711 (Thrombocytopenia)			Pirfenidone (Idiopathic pulmonary fibrosis)	→ (FY2008)
			S-0139 (Cerebrovascular disease)			Adapalene (Acne vulgaris)	→ (FY2008)
		NS75A (Uterine myoma)	NS75B (Benign prostatic hypertrophy)		Duloxetine (Depression)	→ (FY2009)	
						Cetrotide® (FY2006)	

in-house product

*Complicated intra-abdominal infections and Complicated urinary tract infections, including pyelonephritis

DNP: Diabetic Neuropathic Pain, AD: Atopic Dermatitis

- ◆ **Anti-obesity (Oral)**
- ◆ **Neuropeptide Y (NPY) Y5 receptor antagonist**
- ◆ **Key findings from pre-clinical studies**
 - Increased energy consumption
 - Suppressed visceral fat accumulation and improved blood glucose and serum lipid levels
 - Confirmed continuous suppression effect for weight increase without rebound
 - Confirmed excellent safety
- ◆ **Key findings from clinical studies to date**
 - Once-daily administration (T_{1/2} : about 20 hours)
 - No serious adverse events observed
 - Achieved positive results in Phase IIa proof-of-concept study in the USA

Phase IIb studies are under way in the USA

◆ Phase IIb studies:

◆ Two studies: (Total number of patients : 1500)

- Initiated patient enrollment in March 2007 and completed patient enrollment in September 2007
- Scheduled to conduct interim analysis: late March – early April, 2008

◆ Partnering:

- ◆ Started negotiation with a number of pharmaceutical companies to select the favorable candidate for a partner
- ◆ Plan to decide a partner by the time Phase IIb clinical study is completed

USA NDA scheduled for FY2010

- ◆ **Target Indication: Atopic dermatitis**
- ◆ **Treatment for atopic dermatitis which has selective and strong agonist activity to CB2 receptor and has both anti-pruritic and anti-inflammatory efficacy**
⇒ **First in class as a treatment for atopic dermatitis**
- ◆ **Inhibits scratching behavior induced by various pruritogenic agents in mouse model**
- ◆ **Demonstrated anti-inflammatory efficacy in mouse model**
- ◆ **Good safety profile in GLP toxicology studies**
- ◆ **Initiated Phase I multiple dose studies simultaneously in Japan and the USA (2Q FY2007)**

POC studies already started

S-021812 (Peramivir) : Profile



- ◆ Licensed from BioCryst Pharmaceuticals, Inc. (the USA)
- ◆ Anti-influenza virus drug (neuraminidase inhibitor)
- ◆ Highly active against influenza A and B viruses
 - Stronger activity against influenza B virus than Tamiflu
- ◆ Strong activity against the highly pathogenic avian influenza virus (H5N1)
- ◆ Strong binding potency with neuraminidase and resistant to dissociation
 - **Possibly effective even with single administration**
- ◆ Expected to be effective even if administered more than 48 hours later after infection (**delayed administration**)
- ◆ Phase III study is ongoing in the USA by BioCryst (intramuscular injection)
 - Completed Phase I clinical study ⇒ Phase II clinical study on-going**

- ◆ **A novel small-molecule : Thrombopoietine(TPO) receptor agonist**
- ◆ **Target indication:Thrombocytopenia associated with various diseases such as ITP*¹, MDS*² and HCV*³ infection**
 - *1: Idiopathic Thrombocytopenic Purpura
 - *2: Myelodysplastic Syndrome
 - *3: Hepatitis C Virus
- ◆ **Orally active with little food effect and high bioavailability based on animal PK studies**
- ◆ **Efficacy: Increased platelet counts in animal models in a dose-dependent manner with a wide therapeutic window**
- ◆ **Good safety profile in GLP toxicology studies**

Started Phase I clinical study in Japan in September, 2007

- ◆ **Being developed by Shionogi-GlaxoSmithKline Pharmaceuticals, LLC**
- ◆ **HIV Integrase inhibitor (Oral)**
- ◆ **Strong anti-HIV activity by inhibiting virus replication in vitro**
- ◆ **Good resistance profile**
- ◆ **Good pharmacokinetic profile**
- ◆ **Low risk of drug-drug interactions**

S-349572 : Profile

- ◆ **Started Phase I clinical study in the USA in November, 2007**
- ◆ **Confirmed good PK in human**

For Further Inquiries



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