



The 2nd Medium-Term Business Plan



 **SHIONOGI & CO., LTD.**

April 5, 2007

Motozo Shiono

President and Representative Director



Agenda

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I. Outline of the 2nd Medium-Term Business Plan

 **SHIONOGI & CO., LTD.**





Shionogi's Action Guidelines and Positioning of the 2nd Medium-Term Business Plan

Shionogi's Purpose
Shionogi strives constantly to provide medicine of the best possible kind essential for protection of the health of the people

To realize this mission

Shionogi's action guidelines

Established to realize Shionogi's mission (the Shionogi mindset)





II. Progress toward the Goals of the 2nd Medium-Term Business Plan

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Progress toward the Goals of the 2nd Medium-Term Business Plan: Research and Development (1)

- **Enrich the product line for infectious diseases and add pain and metabolic syndrome to new target areas**

Infectious diseases: R&D expanded to include antiviral and other agents
Continued focus on antibiotics

Pain: Progress in the development of a novel pain treatment

Metabolic syndrome: Developed S-2367 as a global strategic product

Frontier areas: Steady progress in selected R&D programs

- **Advance at least 5 new chemical entities to Phase II or more advanced stages by the end of FY 2009 in order to develop blockbusters to succeed Crestor[®]**

S-2367 (Anti-obesity: in Phase II)

S-364735 (Anti-HIV: in Phase II)

S-777469 (Antipruritic treatment: in Phase I)

Promote global development continuously for multiple products



Progress toward the Goals of the 2nd Medium-Term Business Plan: Research and Development (2)

- **Establish a continuous pipeline stream through active licensing activities**
 - ◆ Adapalene (Acne), Peramivir (Anti-Influenza): In-licensing

- **Increase R&D efficiency and success probability by aggressively employing external resources**
 - ◆ Enriched R&D pipeline (Purdue Pharma L.P. in the USA, Hokkaido University)
 - ◆ Studying to out-license a product in a non-core research area (S-0373)
 - ◆ Out-licensed phospholipase A2 program (Anthera Pharmaceuticals, Inc. in the USA)
 - ◆ Joint development agreement with Eli Lilly Japan K.K. (Duloxetine; diabetic neuropathic pain)

- **Maximize product potential through life-cycle management from an early development stage**
 - ◆ Addition of new formulations: OxiNorm[®], Finibax[®] kit product, Claritin[®] dry syrup, Cetrotide[®] sustained release formulation (NS75B)
 - ◆ Expansion of indications: Duloxetine, NS75B, Finibax[®]
 - ◆ Clinical trials for evidence: Crestor[®], Finibax[®], Imunace[®]



Progress toward the Goals of the 2nd Medium-Term Business Plan: Sales and Marketing (1)

- **Further promote information activities for acute treatments by adding Doripenem and Moxifloxacin to the current product line and expand the Company's No.1 market share in the anti-infective field**

FY2006 Review

- **Doripenem (Finibax[®]): Launched in September 2005**
- **Moxifloxacin (Avelox[®]): Launched in December 2005**
- **Lower-than-anticipated growth in the market for injectable carbapenem and new oral quinolone products**
- **Slower-than-anticipated penetration of prescription for severe infection**
 - **Sales of Finibax[®] in FY2006: ¥3.5 billion (revised forecast)* → ¥2.0 billion (latest estimate)**
- **Negative impact by adverse events of the similar class antibiotic and the revision of the product insert for Avelox[®]**
 - **Sales of Avelox[®] in FY2006: ¥3.0 billion (revised forecast)* → ¥2.4 billion (latest estimate)**

* : revised in November 2006



Progress toward the Goals of the 2nd Medium-Term Business Plan: Sales and Marketing (2)

- **Relieve patients from cancer pain and further improve quality of life. Implement information activities aiming at total pain relief**

FY2006 Review

➤ **OxiNorm[®]: Launched in February 2007**

- **Made progress in expanding prescriptions to manage early-stage cancer pain by switching from MS Contin[®] to OxyContin[®]**

- **However, there is a move to switch from low doses of OxyContin[®] to Fentanyl patches due to insufficient promotional activities of oral administration, that is generally recommended by the World Health Organization**

- **Sales of OxyContin[®] in FY2006: ¥7 billion (revised forecast)* → ¥ 5.1 billion (latest estimate)**

- **Maximize Crestor's value by collecting the necessary clinical evidence and by establishing confidence in the product through thorough post-marketing surveillance studies**

FY2006 Review

➤ **Crestor[®]: Moved to regular promotional activities in September 2006**

- **Earlier-than-anticipated post-marketing surveillance results (Confirmed efficacy and safety)**

- **Insufficient supporting evidence for domestic dosage range and the delay in disseminating the lipid management guidelines “the lower, the better” concept for LDL management**

- **Sales of Crestor[®] in FY2006: ¥4 billion (revised forecast)* → ¥ 2.5 billion (latest estimate)**

*** : revised in November 2006.**



Progress toward the Goals of the 2nd Medium-Term Business Plan: Sales and Marketing (3)

- **Expand marketing synergy and the efficiency of information activities by introducing multi-product promotion methods for each target disease and medical specialty**
FY2006 Review
 - Resulted in uncompetitive strategies for multi-product promotion method due to insufficient preparation for new product launches

- **Strengthen sales support activities by creating an organization-wide support system**
FY2006 Review
 - Began promoting product life-cycle management and other initiatives through the Therapeutic Area Conference (TAC)
 - Established quick response to medical needs through cross-functional relationship among Research, Development, Drug Safety Management and other divisions

- **Strengthen training of medical representatives so they can accurately perceive medical needs and make suggestions about medical treatment options**
FY2006 Review
 - Assigned MRs specializing in the cardiovascular field (August, 2006)



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

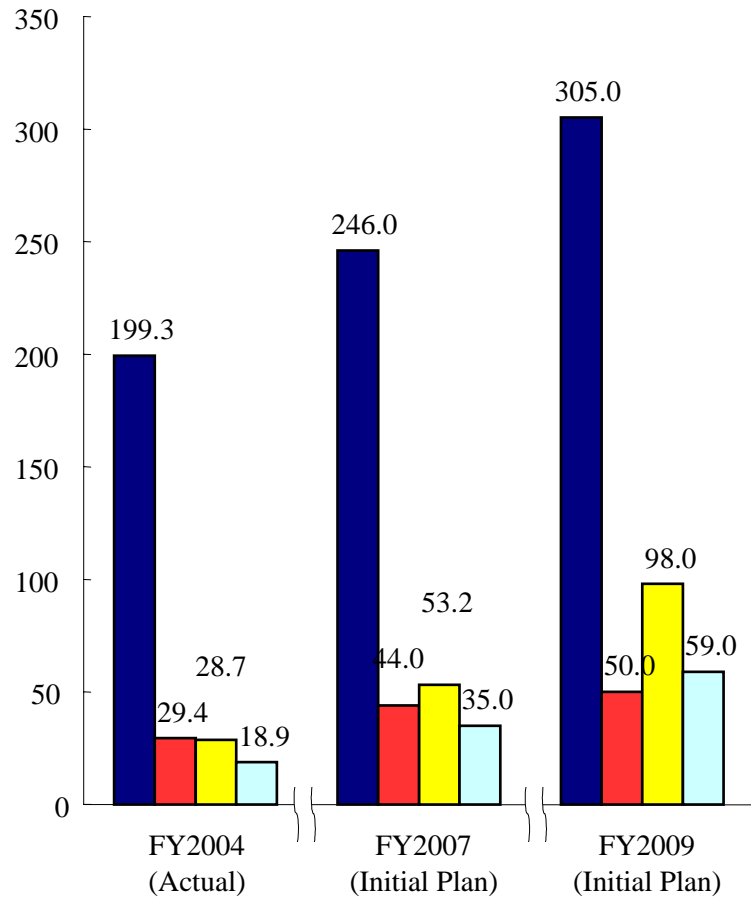
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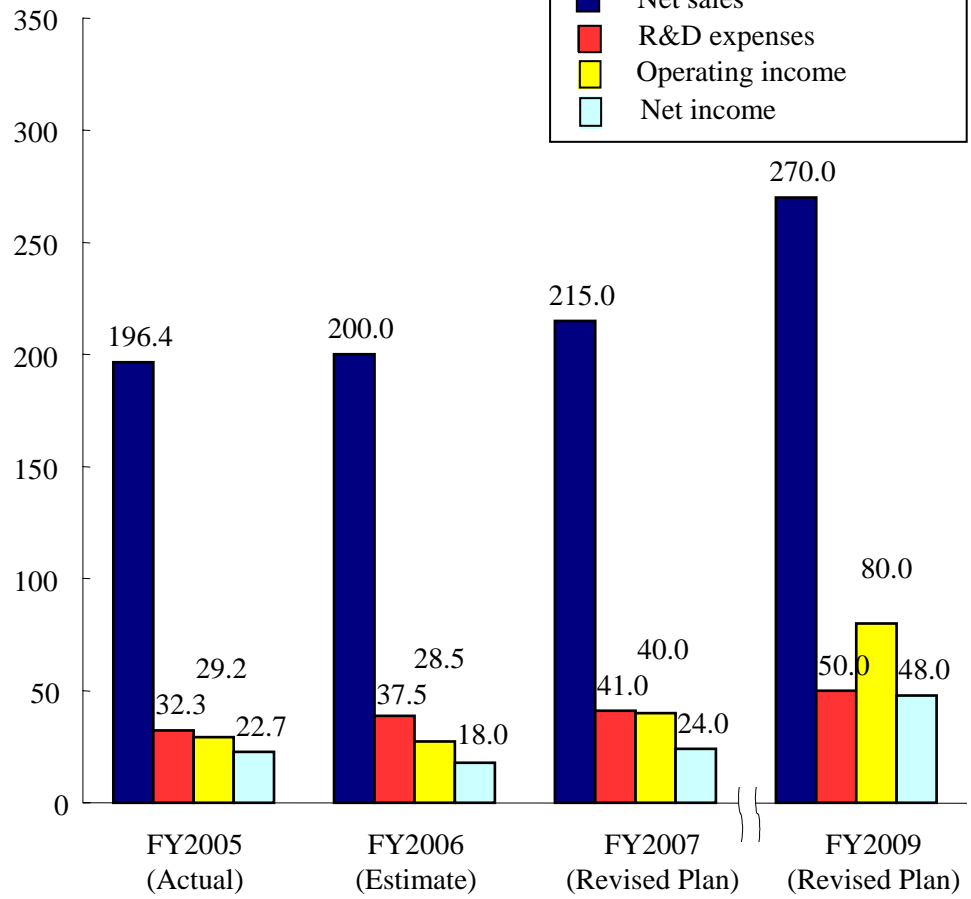
Revised Consolidated Financial Targets for the 2nd Medium-Term Business Plan

(Billions of yen)



Initial Plan

(Billions of yen)



Revised Plan



Sales Targets by Segment

(Billions of yen)

	FY2005 Actual	YoY Change (%)	FY2006 Estimate	YoY Change (%)	FY2007 Target	YoY Change (%)	FY2009 Target
Pharmaceuticals and related businesses	187.2	1.7	192.2	2.7	210.6	9.6	267.9
Prescription drugs	159.7	-1.5	152.1	-4.8	158.3	4.1	176.3
Export/Overseas operations	5.8	28.6	5.4	-6.9	6.3	16.7	12.7
Contract manufacturing	2.1	60.8	4.0	90.5	6.0	50.0	7.5
OTC and quasi-drugs	6.4	1.6	6.1	-4.7	6.4	4.9	6.7
Diagnostics	3.4	-5.2	3.3	-2.7	3.6	9.1	4.7
Royalty income	9.8	61.3	21.3	117.3	30.0	40.8	60.0
Capsule business	6.1	-49.1	-	-	-	-	-
Others	3.1	-8.9	7.8	151.6	4.4	-43.6	2.1
Total	196.4	-1.5	200.0	1.8	215.0	7.5	270.0



Analysis of Variance between FY2009 Original and Revised Sales Targets

(Billions of yen)	Increase (Decrease)	
Total	(35.0)	
Prescription drugs :	(37.5)	
Existing products (Antibiotics)	(11.1)	
Existing products (Others)	(17.5)	
New products	4.8	
Projected sales from possible in-licensing	(13.7)	
Sales from businesses other than prescription drugs :	2.5	
Royalty revenues from licensing fees	0.0	
OTC drugs and diagnostics	(0.9)	
Export/Overseas operations	5.9	← Due to increase of export sales of bulk Doripenem to J&J
Contract manufacturing	(0.5)	
Others	(2.0)	← Due to decrease in construction contracts at Shionogi Engineering Service



Factors Affecting Sales and Marketing Targets

	FY2009
	Main factors
Existing products	
Flomox [®]	<ul style="list-style-type: none"> • Contraction of oral cephem antibiotic market greater than anticipated • Promotion resources concentrated on new products
Flumarin [®]	<ul style="list-style-type: none"> • Greater-than-anticipated expansion of DPC* system resulted in shift to less expensive products/generic products, decreased dosing days • Promotion resources concentrated on new products
Injectable Vancomycin [®]	<ul style="list-style-type: none"> • Competition from additional indication for MRSA for Rinezorid
OxyContin [®]	<ul style="list-style-type: none"> • The number of prescriptions has been increasing smoothly, but average dose per day has been lower than anticipated as a result of weak dissemination of WHO's "oral administration as a general rule" guideline
Claritin [®]	<ul style="list-style-type: none"> • Market share forecast revised downward because market competition has been tougher than anticipated • Delay in launch of pediatric formulation
Others	<ul style="list-style-type: none"> • Slower-than-anticipated progress of multi-product promotion activity to achieve sales expansion targets for Landel[®], Rhythmy[®] and others
New products	
Crestor [®]	<ul style="list-style-type: none"> • Sales forecast revised upward as a result of (1) shortening the PMS period (2) smooth progress in building up supporting evidence like COSMOS study (3) concentrating promotion resources
Finibax [®]	<ul style="list-style-type: none"> • Prescriptions and adoption by hospitals have been expanding as planned, but physician prescriptions for serious infection have lagged (Supporting evidence generated from 2008 in Japan and overseas countries expected to support expansion in perscriptions)
Avelox [®]	<ul style="list-style-type: none"> • Initial sales impacted by adverse events associated with the similar class compound and subsequent revision of product insert (Aim to achieve originally targeted market share by using supporting evidences effectively in our information activities)
Other new products	<ul style="list-style-type: none"> • Revised sales forecast upward for Pirfenidone and Irbesartan
In-license	
Defferine	<ul style="list-style-type: none"> • Change in expected NHI price resulting from changes to the NHI pricing system
Others	<ul style="list-style-type: none"> • Unsuccessful final negotiation

*DPC: Diagnosis Procedure Combination

Analysis of Variance between FY2009 Original and Revised Operating Income Targets

(Billions of yen)

(Billions of Yen)	Original target for FY2009	Revised target for FY2009	Increase (Decrease)
Sales	305	270	(35.0)
[Royalty revenues]	[60]	[60]	
	28.9 (36.0)	27.8 (35.7)	
Cost of Sales	88.2	75.0	(13.2)
SG&A expenses	118.8	115.0	(3.8)
[R&D Expenses]	[50]	[50]	0.0
Operating income	98.0	80.0	(18.0)

Variance in operating income (18.0)

Decrease in sales (22.4)

Change in cost of sales ratio

0.6 { Due to change of product composition in sales forecast
Due to continuous efforts to decrease costs

Decrease in SG&A expenses

3.8 { Due to decrease of selling expenses in proportion to sales amount
Due to decrease of ordinary and indirect divisions' expenses



IV. New Challenges for FY2007 and Beyond

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Sales and Marketing: New Challenges for FY2007 and Beyond (1)

- **Expand market share by concentrating resources on new products (Crestor[®], Avelox[®], Finibax[®])**
 - **Introduce a new way for creating sales targets for MRs, based on market share analysis in each region**
 - **Review and optimize MR allocation**
 - **Introduce a new performance evaluation system and an incentive plan with the aim of increasing sales of new products**
- **Establish the Cancer Pain Management Business Development Department and enhance activities to disseminate information on cancer pain treatment**
 - **Disseminate and expand information on cancer pain treatment in cooperation with authorities, academic institutions and other companies**
 - **Enhance the quality of cancer pain management by widely spreading the use of OxiNorm[®] (immediate release formulation)**
 - **Disseminate WHO system (cancer pain management by oral administration) and promote higher OxyContin[®] dosings by increasing the adoption rate for 40mg tablets at hospitals**
 - **Start a corporate advertising campaign that promotes a pain-free society**



Sales and Marketing: New Challenges for FY2007 and Beyond (2)

- **Strengthen information activities at advanced treatment hospitals***
 - Enhance responsiveness of information activities by assigning a full-time manager to the Tokyo office reporting directly to marketing divisions
 - Strengthen specialist training for MRs responsible for advanced treatment hospitals
 - Promote communications with medical specialists and understanding of medical needs by increasing the frequency of web-conferences using e-media
- **Promote area marketing**
 - Assign marketing plan facilitators to interface between the Marketing Division and MRs (Tokyo & Osaka)
 - Further strengthen the system to support sales and marketing strategy through cross-functional TACs

* medical institutions certified by the government as having sufficient functions and capabilities to provide, research, develop and evaluate advanced treatment for specified diseases



Overseas Business Development: Agenda for FY2009 (1)

Agenda for FY2009

Research Division

Continuously discover globally competitive drugs

Ensure FTIH* for 2 or more in-house new drug candidates each year

Development Division

***FTIH: First Trial In Human**

Simultaneously develop multiple in-house products in Japan, the USA and the EU

1. Development of global strategic products

Promote overseas activities with S-2367, S-364735 and S-777469

Continuously discover compounds competitive in global markets to follow the above 3 products

2. Construct a functional organization and invest effectively in R&D

Streamline strategic core organization to promote simultaneous development in Japan/USA/EU and develop human resources

Concentrate investment in developing opportunities for royalty revenues

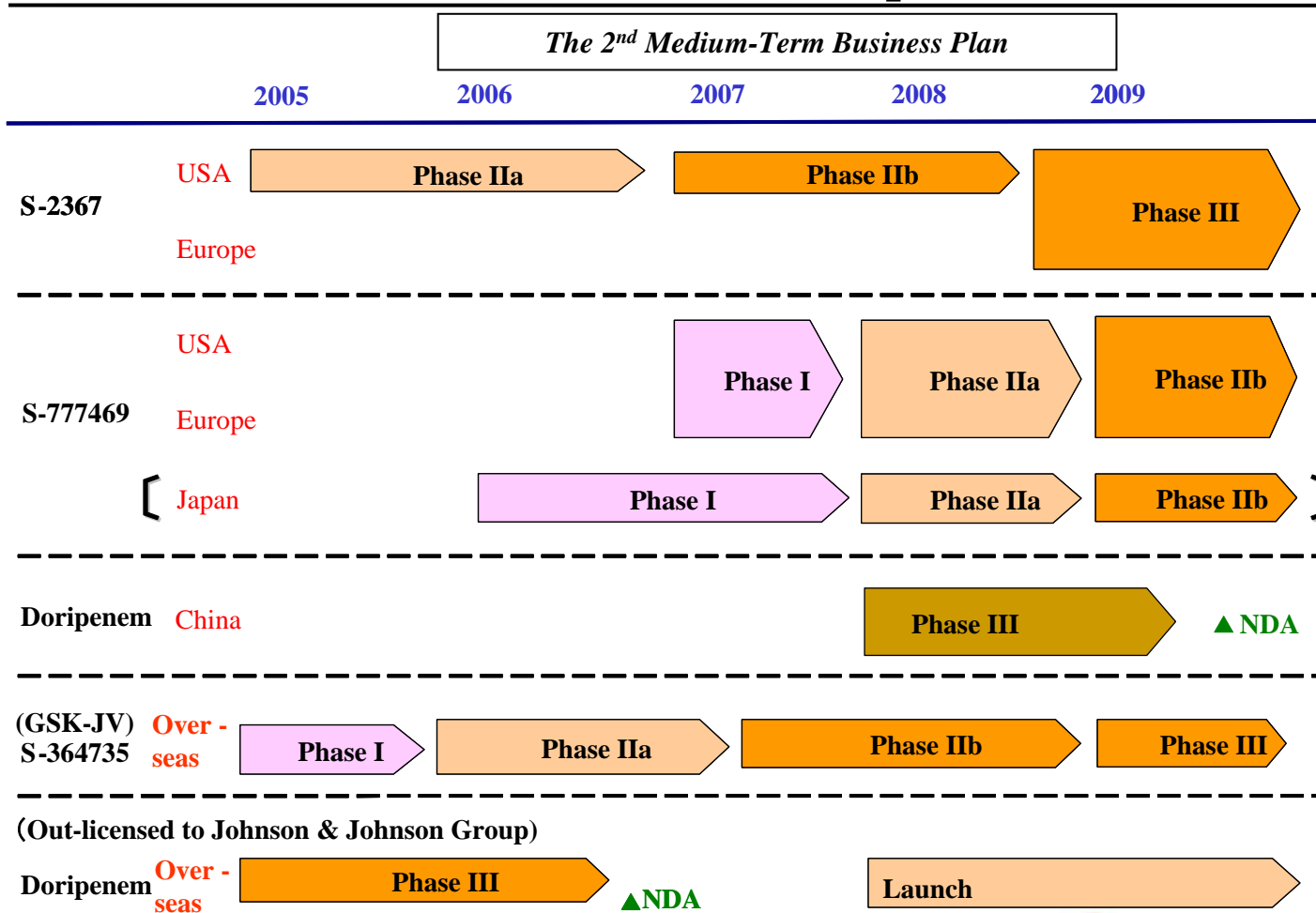
3. Positively seek business opportunities

Accelerate global development through strategic alliances



Overseas Business Development: Agenda for FY2009 (2)

Overseas Business Development Plan





Development Status and Launch Schedule for New Drugs (As of March 2007)

	DCS	Ph I/Ph IIa	Ph IIb	Ph III	Files	Launch
Three targeted R&D areas			S-013420 (Bacterial infection)		Doripenem (Bacterial infection)	(2008 or later by Johnson & Johnson)
		Peramivir (Influenza)	S-364735 (HIV infection)			Finibax [®] kit product (FY2006)
		Final review stage for in-licensing (Non-cancer pain treatment)	Duloxetine (DNP)			OxiNorm [®] (FY2006)
Pain	★	Final review stage for in-licensing (Insulin sensitizer)	S-2367 (Anti-obesity)		Irbesartan (Hypertension)	(FY2008)
MS		Final review stage for in-licensing (Lipid-lowering agent)				
Frontier areas	★	S-777469 (Pruritus resulting from AD)			Claritin [®] (New formulation)	(FY2007)
					Pirfenidone (Idiopathic pulmonary fibrosis)	(FY2008)
Others	★				Adapalene (Acne)	(FY2008)
	★	S-0139 (Cerebrovascular diseases)		Duloxetine (Depression)		(FY2009)
	★	NS75A (Uterine myoma)	NS75B (Benign Prostatic Hypertrophy)			Cetrotide [®] FY2006

DNP: Diabetic Neuropathic Pain, AD: Atopic Dermatitis



Measures to Achieve Cost of Sales and SG&A Expense Targets

Cost of sales

- **Increase investment in manufacturing site**
- **Increase Doripenem production volume to improve manufacturing efficiency**
- **Further decrease manufacturing and procurement costs**

SG&A expenses

- **Maintain original forecast for R&D expenses for FY2009 because of smooth progress in R&D programs**
- **Increase number of MRs from 1,400 to 1,500**
(Planning to decrease consolidated number of company employees by about 100 from just under 5,000 at present)
- **Increase strategic sales & marketing expenses to strengthen sales organization**
- **Decrease ordinary and indirect division expenses company-wide**



Investment in Future Progress

*Strengthen drug discovery
research for drug “seeds”*

*Aggressively pursue in-licensing
to establish continuous pipeline
stream*

**60 billion yen investment
from FY2007 to FY2009**

*Aggressive investment
focused on manufacturing
and R&D*

*Enhance organization for
overseas business
development*



Fundamental Policy for Dividends

- **Prioritize investment for medium-to-long-term growth**
- **Fundamental policy on appropriation of retained earnings**

< Payout ratio >

FY2006 forecast: 30%

FY2009 target: 35%



Summary: Shionogi's Action Guidelines and Positioning of the 2nd Medium-Term Business Plan

Shionogi's Purpose
Shionogi strives constantly to provide medicine of the best possible kind essential for protection of the health of the people

To realize this mission

Shionogi's action guidelines

Established to realize Shionogi's mission (the Shionogi mindset)





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