

# The 4th Medium Term Management Plan FY Feb. 2010 - FY Feb. 2014

This presentation material contains information that constitutes forward-looking statements. Such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and actual results may differ from those in the forward-looking statements as a result of various factors including changes in material circumstances.

Hisamitsu Pharmaceutical Co., Inc.

July 27, 2009

Patch and Care of People around the World

## The 4th Med-Term Management Plan Background and Challenge

**Increasingly severe Japan market**  
(Pressure to lower drug costs, slowdown in spending)

**Increasingly severe competition**  
(Competitive products, GEs, PBs, food for specified health use)

**Growing overseas market**  
(Population growth, aging society)

Our strengths which have obtained growth of sales and profit mainly in Japan

**Differentiation**  
(Differentiation in sales activities)  
(Differentiation in products)

**Our brand**  
(Japan, Asian countries)

**Focus on TDDS technology**  
(Production efficiency, investment in R&D)

**Our challenge to continue growth**

**Creation and growth of new products**

**Obtaining competitive edge outside Japan**

**Accomplished organization power**

# The 4<sup>th</sup> Med-Term Management Plan Basic Principle

**1) Strengthening difference in products and sales activities**

**2) Obtaining competitive edge outside Japan**

**3) Strengthening TDDS R&D**

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## 1) Strengthen differences in products and sales activities

Continued improvements which fit customers' needs

### Ethical Pharmaceutical

Increase of MRs, building a sales structure which realizes sufficient calls for existing / new products.

- Target JPY97 billion; total of Mohrus and Mohrus Tape (Share > 54% in 2<sup>nd</sup> generation NSAID patches)
- Target > JPY20 billion; Total of HFT-290 and BTDS

### OTC

Addition of items, continued launch of new products

- Expand current top shares in external analgesic anti-inflammatory patches (share > 40%) and athlete foot products (share > 30%)

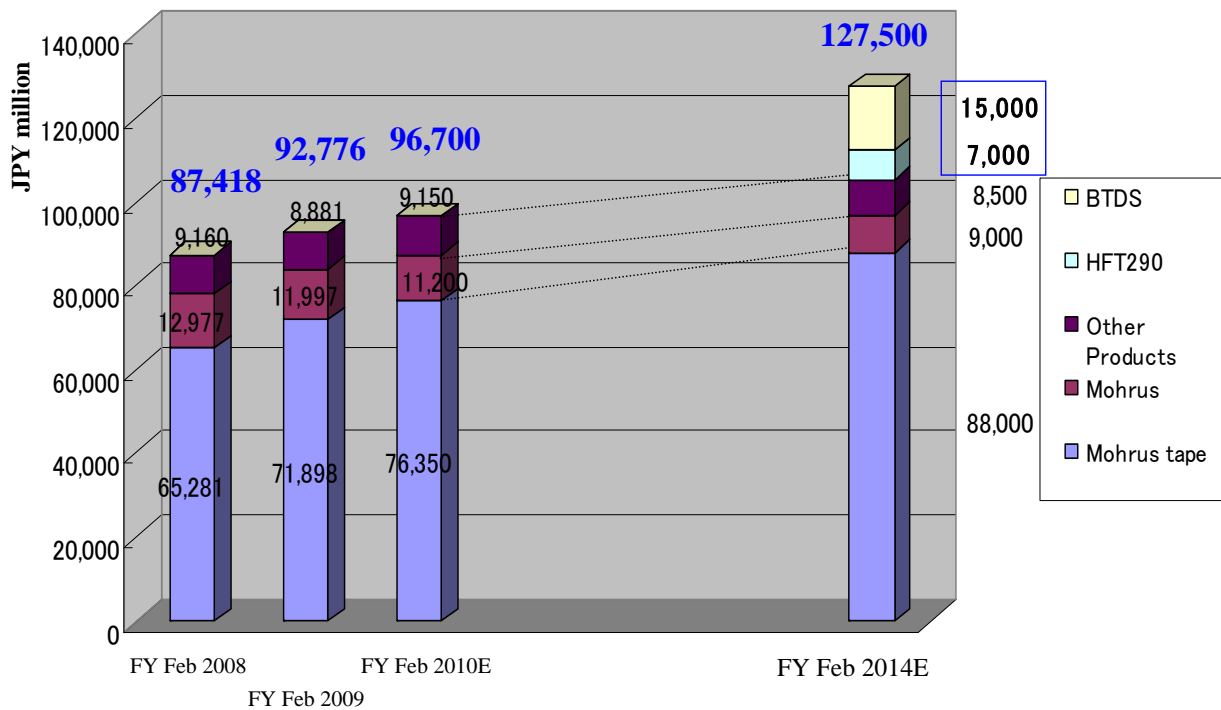
**Continued enhancement of added-value and brands of domestic business**

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# Ethical Pharmaceutical - Sales Target (Domestic)

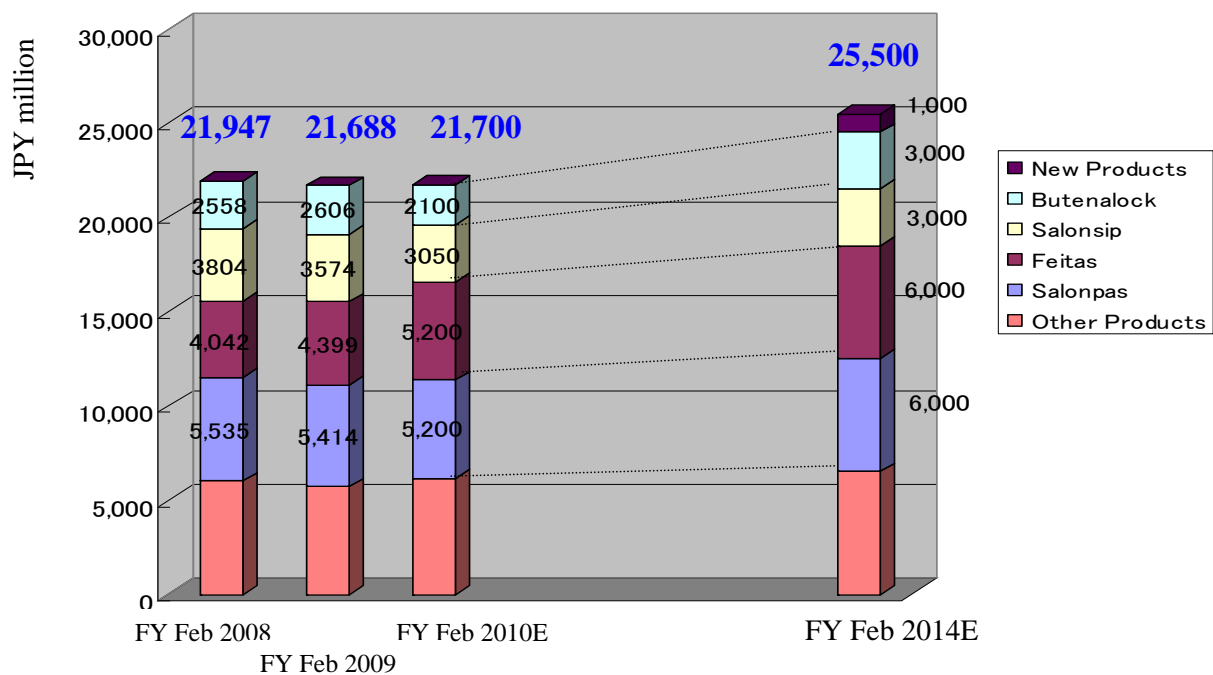
CAGR (+6.6%)



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# OTC Sales Target (Domestic)

CAGR (+3.3%)



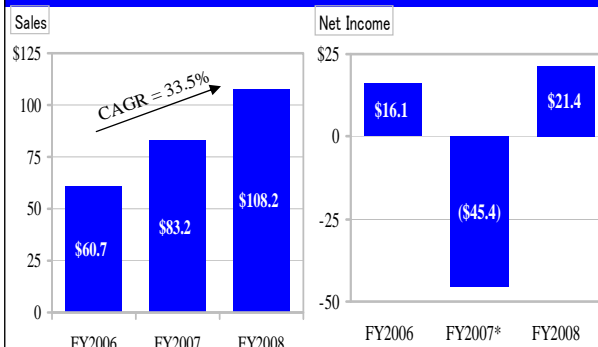
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# Overview of Noven Pharmaceuticals

## Overview

- Headquarters: Miami, Florida, USA
- Established: 1987
- Sales (FY2008): US\$108.2million
- Net Profit (FY2008): US\$21.4million
- Stock Listing: NASDAQ
- Market Cap (as of Jul. 13, 2009): US\$335.8million
- Number of employees (as of Dec. 31, 2008): 610

## Sales and net profits (US\$ million)



\*Including in-process R&D cost due to JDS Pharmaceuticals

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# Products on the Market

Products <sup>(1)</sup>	Indication	Mode of action
<b>Noven Therapeutics</b>		
 Pexeva <sup>®</sup> Tablets (paroxetine mesylate)	■ Depression, Panic Disorder, OCD, GAD	■ Selective Serotonin Reuptake Inhibitor (SSRI)
 LITHOBID <sup>®</sup> (Lithium Carbonate, USP) Extended-Release Tablets, 300 mg	■ Bipolar disorder	■ GSK-3 $\beta$ inhibitor
 Stavzor <sup>®</sup> (valproic acid delayed release capsules)	■ Bipolar disorder, Migraine, Seizures	■ GABA-T inhibitor
<b>Noven Transdermals</b>		
 VIVELLE dot <sup>®</sup> (estradial transdermal system)	■ Menopausal syndrome, Osteoporosis	■ Estradiol transdermal system
 Combi patch <sup>®</sup> (estradion/norethindrone acetate transdermal system)	■ Menopausal syndrome, Osteoporosis	■ Estradiol/norethindrone acetate transdermal system
 Daytrana <sup>®</sup> (methylphenidate transdermal system)	■ ADHD	■ Norepinephrine and dopamine reuptake inhibitor

(1) DentiPatch (topical anesthesia prior to superficial dental procedures) is sold by several independent marketers.

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# Product Pipelines

Product	Comments
Noven Therapeutics	
Mesafem	<ul style="list-style-type: none"> <li>■ Indication: Vasomotor symptoms (VMS) associated with menopause</li> <li>■ Oral formulation of low-dose paroxetine mesylate</li> <li>■ Uncertain, and promising pipeline product targeting 23 million VMS patients in US</li> <li>■ Current stage: Phase 2</li> <li>■ Launch: Expecting approximately 2H 2011</li> <li>■ Non-hormonal product, Mode of action: GABA-T inhibitor</li> </ul>
Noven Transdermals	
Amphetamine Patch	<ul style="list-style-type: none"> <li>■ Indication: ADHD</li> <li>■ Pre-clinical</li> <li>■ Mode of action: Norepinephrine and dopamine reuptake inhibitor</li> </ul>
Testosterone Patch	<ul style="list-style-type: none"> <li>■ Indication: Hypoactive Sexual Desire Disorder (HSDD) in post-menopausal women</li> <li>■ Partnered with P&amp;G Pharmaceuticals</li> <li>■ Product: Low-dose testosterone patch</li> </ul>

# U.S. Bases



## 2) Obtaining Competitive Edge outside Japan

Improve the presence of Hisamitsu Pharmaceutical in countries of foreign operations.

### Asia

- Entry to new countries such as China
- New products to existing countries and continued advertising investment
- Building up sales infrastructure and bases in each country
- Lowering cost of goods with utilizing manufacturing subsidiary in Asian countries

### U.S.A.

- Planning and performing sales strategy of FDA approved products.
  - ✓ HFG-512, HKT-500
- To strengthen distribution to chain stores and marketing of 'Salonpas Pain Relief Patch' and 'Salonpas Arthritis Pain'

**Building up business infrastructure and to realize  
15% of overseas sales**

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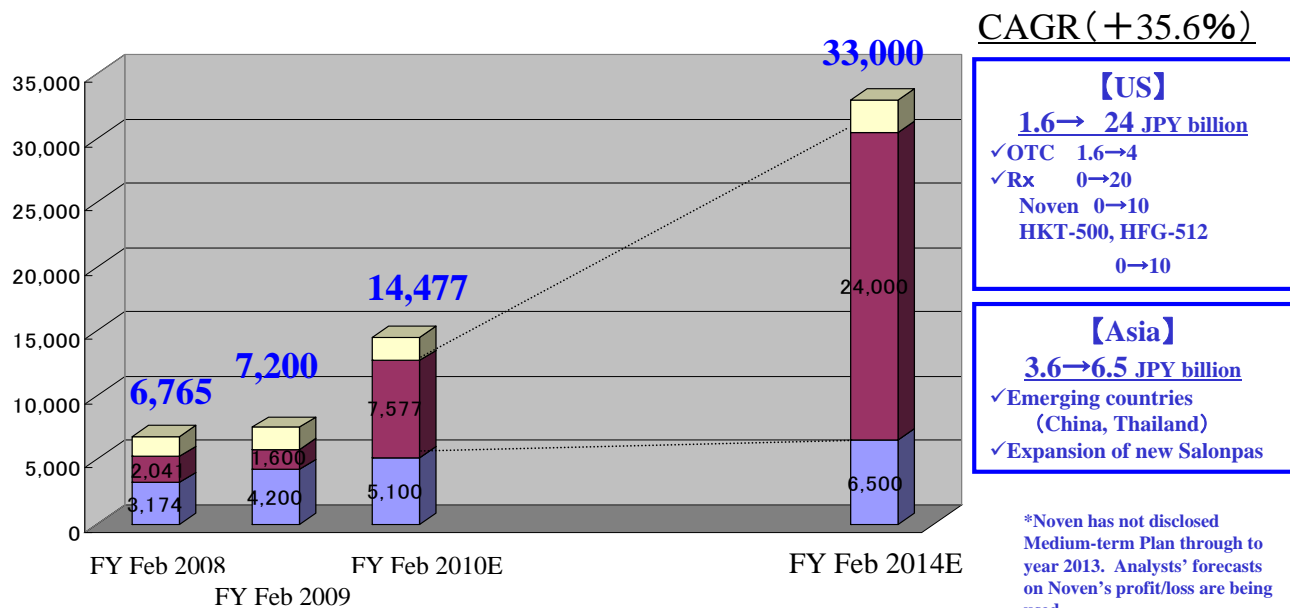
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## Med-Term Overseas Sales

FY Feb. 2009 Approx. JPY7 billion (5% of total sales)



FY Feb. 2014 JPY33 billion (15% of total sales)



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### 3) Strengthening TDDS R&D

- Integration of know-how of clinical development in Japan and US to result in shortening development period
- Integration of TDDS formulation technologies to realize a number of new TDDS formulations

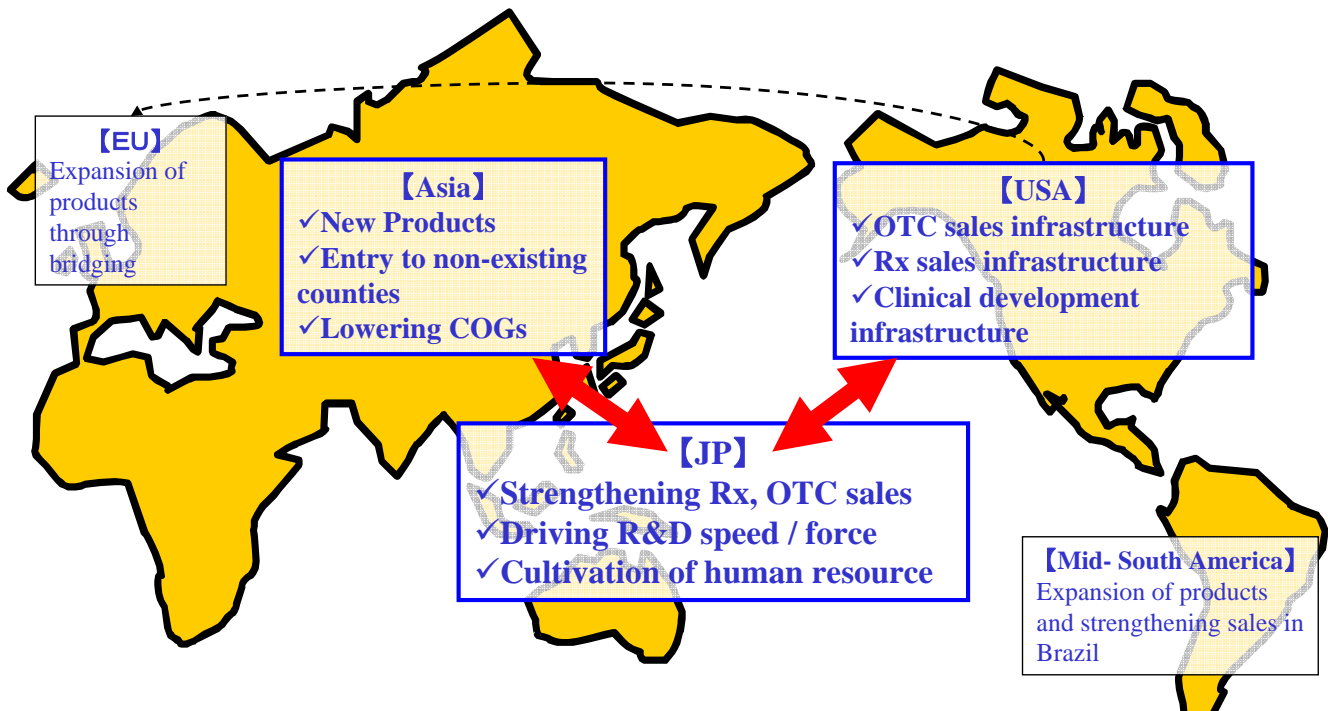
**Skill up of clinical development and realizing new TDDS formulations**

### R&D Pipeline – Med-Term Forecast

	Code	Formulation	1Q, 2009	FY2010E	FY2011E	FY2012E	FY2013E
<b>JP</b>	HFT-290	TDDS	Filed	Approved			
	BTDS	TDDS	Filed	Approved			
	KPT-220	TDDS	Filed	Approved			
	HTU-520	TDDS	P II				P III Completed
	HOB-294	TDDS	P II				P III Completed
<b>US</b>	HFG-512	TDDS	Filed	Non-disclosed			
	HKT-500	TDDS	P III			Approved	
	Mesafem (Noven)	Oral	P II		Approved		
	Amphetamine (Noven)	TDDS	Pre-clinical				-
	Testosterone (Noven + P&G)	TDDS	On-hold				-
	Non-disclose		Up to P I				P III Completed 1 P III 1 P II 3



# Target of the 4<sup>th</sup> Med-Term Management Plan



**Acceleration of growth in US and Asia in addition to Japan**

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## Profit/Loss in the 4<sup>th</sup> Med-Term Management Plan

- **FY Feb 2014 Sales: JPY190 billion Operating profit: JPY43.5 billion**
  - Compatible growth of consolidated sales and conservation of profit rates (Sales, Average annual growth rate: +8%)

<Actual and Targets in Med-Term\*>

Consolidated	2007.2	2008.2	2009.2	2010.2E 1st yr of Med-Term	2014.2E 5th yr of Med-Term
Net Revenue	109,791	119,061	124,656	128,600	190,000
Operating Profit	26,134	29,071	32,532	32,800	43,500
Ordinary Profit	27,001	30,204	32,477	33,100	48,300
Net income	15,847	18,663	19,120	19,800	29,000
(Profit/Share ¥)	178.74	210.45	215.63	225.84	330.74
Rate of RD Cost	8.5%	9.4%	7.7%	6.7%	10.0%
Rate of Overseas Sales	5.4%	5.7%	5.9%	6.5%	15.0%
% of operating profit	23.8%	24.4%	26.1%	25.5%	22.9%
% of ordinary profit	24.6%	25.4%	26.1%	25.7%	25.4%
% of net income	14.4%	15.7%	15.3%	15.4%	15.3%

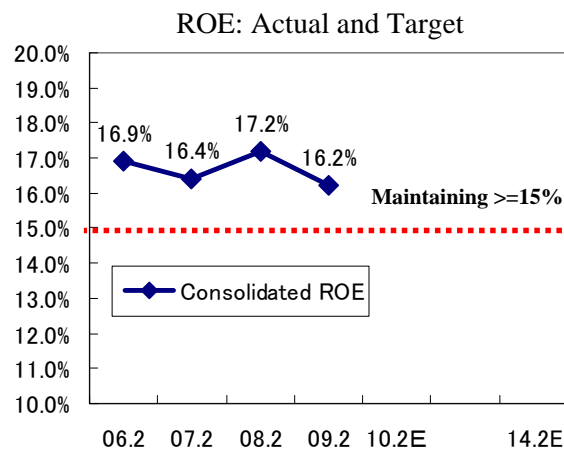
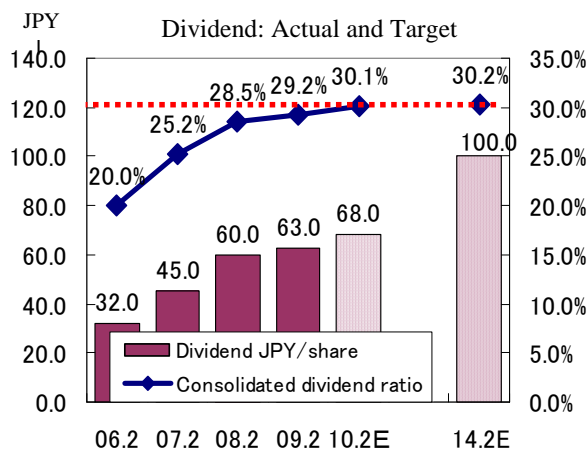
\* Costs for integration such as cost for purchase, amortization of goodwill, in-process R&D cost are not included in Med-Term Profit/Loss target.

\* Noven has not disclosed Med-Term Plan through to year 2013. Analysts' forecasts on Noven's profit/loss are being used.



# Dividend Policy and Equity Policy

- **Basic Policy**
  - To realize long-term stable dividend considering future strategic investment policy
  - To perform flexible share buyback according to conditions such as share price
- **Target**
  - Consolidated dividend ratio **Maintaining  $\geq 30\%$**  (FY Feb 2014 E ¥100/share\*)
  - Consolidated ROE **Maintaining  $\geq 15\%$**



\* FY Feb 2014

Based on consolidated net income JPY 29 bill

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## “Improving Quality of Life (QOL) for People in the World”

The 4<sup>th</sup> Med-Term Management Plan

July 27, 2009

Hisamitsu Pharmaceutical Co., Inc.

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