



# Hisamitsu Pharmaceutical Co., Inc.

## FY02/2008 Results

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.

Apr 8th, 2008

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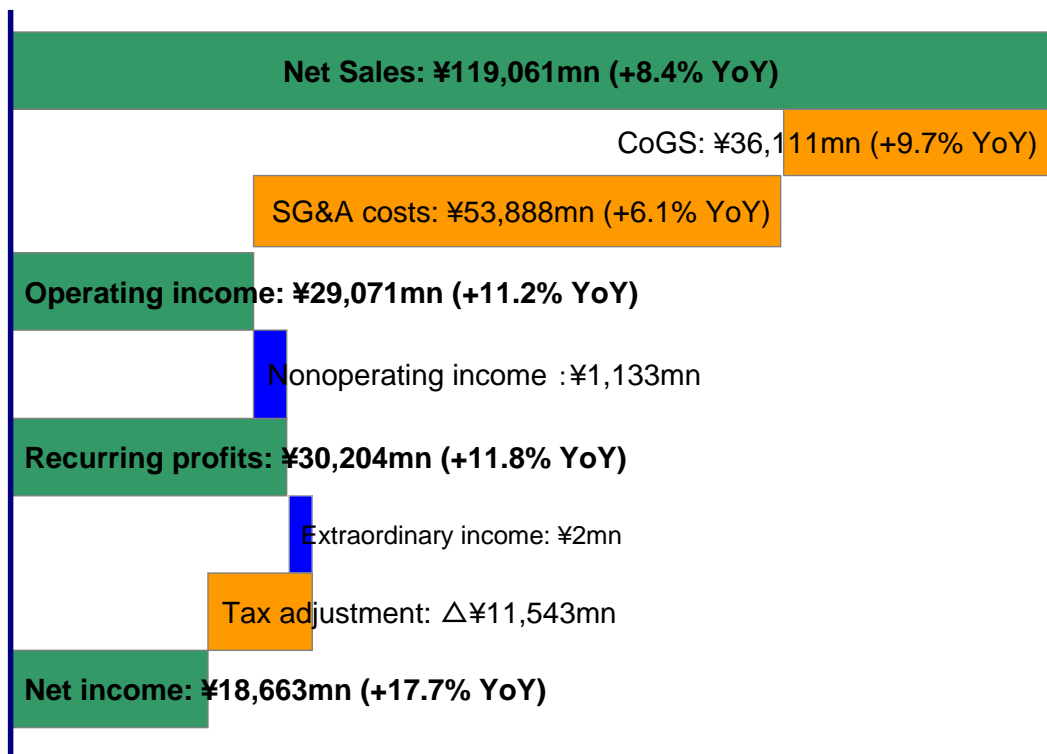
## Business Performance for the Period Ending FY02/2008

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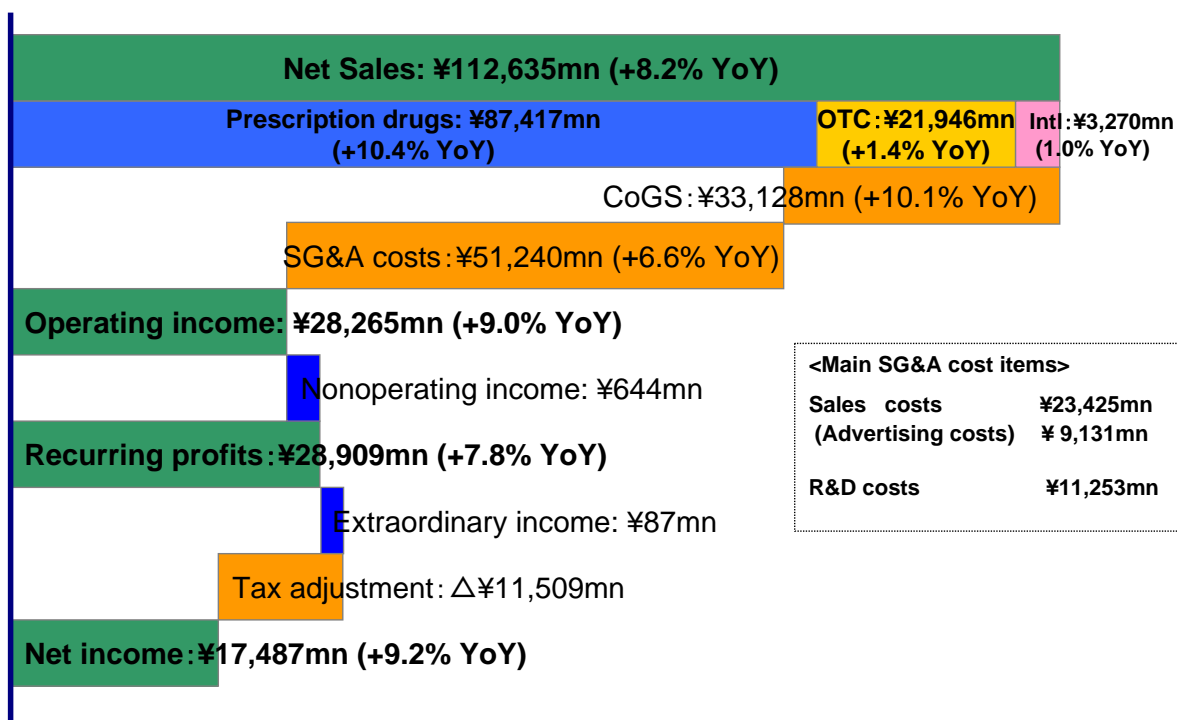
# Consolidated P/L



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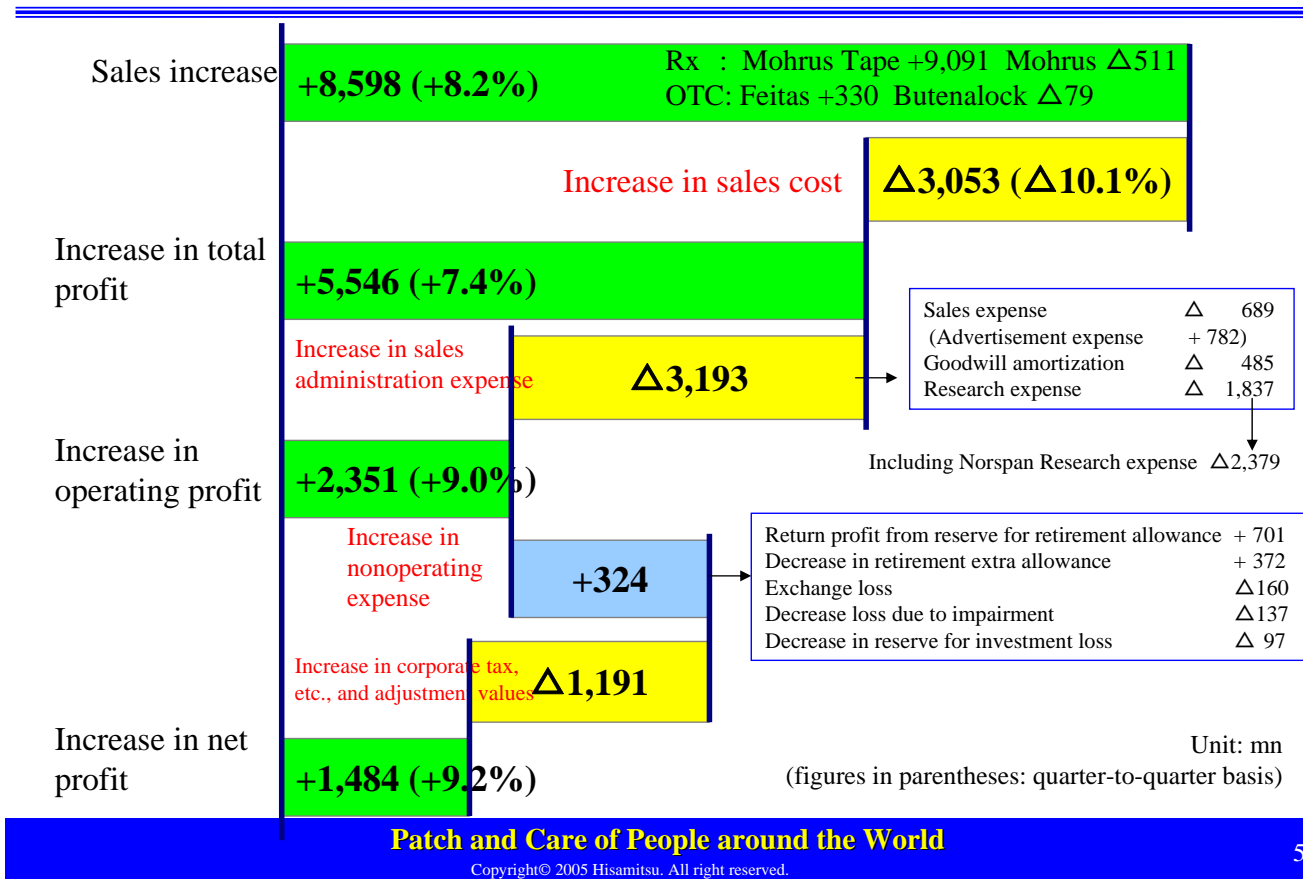
# Non-consolidated P/L



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# Profit and Loss Summary (Unbundling)



## Progress of the Mid-term Business Plan

# Progress of the Targeted Profit and Loss in the Mid-term Business Plan (announced on May 2006)



- The 3-year plan was fulfilled ahead of schedule, thanks to the changes in the market environment and growth of mainstay products**

Unit: ¥ million

Consolidated	07.2E	08.2E	09.2E	07.2 results	08.2 results	YoY	Difference
Sales	107,100	114,000	117,000	109,791	119,062	108.4%	+9,271
Operating income	24,600	26,600	27,300	26,134	29,072	111.2%	+2,938
Recurring profits	25,400	27,100	27,800	27,001	30,205	111.9%	+3,204
Net income	14,500	15,600	16,000	15,847	18,663	117.8%	+2,816
Non-consolidated	08.2E	08.2E	09.2E	07.2 results	08.2 results	YoY	Difference
Sales	102,000	108,000	111,000	104,037	112,635	108.3%	+8,598
Rx Business Division	77,500	83,000	85,000	79,169	87,418	110.4%	+8,249
OTC Business Division	21,000	21,300	22,000	21,496	21,947	102.1%	+451
International Division	3,100	3,200	3,400	3,237	3,270	101.0%	+33
Operating income	24,400	25,800	26,700	25,914	28,265	109.1%	+2,351
Recurring profits	25,200	26,300	27,200	26,805	28,910	107.9%	+2,105
Net income	14,600	15,100	15,600	16,002	17,487	109.3%	+1,485

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# Targeted Sales and Results of Main Products



- Dramatic increase in Mohrus Tapes and steady performance of OTC products**

Unit: ¥ million

	07.2E	08.2E	09.2E	07.2 results	08.2 results	YoY	Difference
Mohrus Tape	54,000	58,800	61,000	56,190	65,281	116.2%	+9,091
(Mohrus Tape)	37,400	39,300	39,500	37,609	40,046	106.5%	+2,437
(Mohrus Tape L)	16,600	19,500	21,500	18,580	25,235	135.8%	+6,655
Mohrus	13,500	13,200	12,300	13,490	12,977	96.2%	513
Naboal group	2,100	3,500	4,600	2,026	2,073	102.3%	+47
Inside Pap	1,300	1,200	1,100	1,325	1,158	87.4%	167
Salonpas	6,400	6,500	6,600	6,801	6,902	101.5%	+101
Salonsip	4,000	4,000	4,000	4,115	4,189	101.8%	+74
Air-Salonpas	1,650	1,650	1,650	1,659	1,762	106.2%	+103
Butenalock	2,300	2,400	2,500	2,637	2,558	97.0%	79
Feitas	3,500	3,700	4,000	3,712	4,042	108.9%	+330

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## ➤ Initial anticipation

- Entry of competitive Rx patch products
- Revision of medical insurance system (expansion of elderly people's self-payment burden)
- Expansion of prescriptions of GE (prescription format that are signed when drug switches are allowed)
- Additional reduction of NHI prices
- Shrinkage of the OTC market and stiffening of competition

## ➤ Current status

- Response to competitive prescription pharmaceuticals being implemented
- Change in schedule of medical insurance system revisions
- Influence of GE switchover mild (product differentiation)
- Optimization of the NHI price reduction range
- Calming down of the OTC market (however, this differs depending on the sector)

**Positive environmental changes to Hisamitsu**

# Progress of the Mid-term Business Plan's Fundamental Policy 1

## Fundamental policy

### 1) Continuation of Hisamitsu's business operation in Japan

- (1) Capture a 50% share in the second-generation external-use anti-inflammatory analgesic market, and sales of ¥77 billion (NHI price-basis)
- (2) Achieve sales of ¥22 billion in the drug cosmetics business department (average annual growth rate of 4.2%)

### 2) Consistent progress of R&D projects by selection and concentration

- (1) File application of HFT-290 (opioid product; Japan) before Feb. 09.
- (2) PIII study should be under way in Feb. 09 for HPL-509 (Parkinson's disease; Japan)
- (3) Development will be promoted for the three themes whose drug product design has been completed, by selecting joint development partners.

## Progress status

### 1) Continuation of Hisamitsu's business operation in Japan

- (1) Share of Mohrus group + Mohrus Tape group was 49.5%, and sales were ¥78.1 billion (NHI price-basis)
- (2) Sales of ¥21.9 billion in the drug cosmetics business department (up 2.1% from the previous term)

### 2) Consistent progress of R&D projects by selection and concentration

- (1) HFT-290: Proceeding as planned.
- (2) HPL-509: Suspended because of adverse reaction information. Currently being re-evaluated.
- (3) Development is being promoted for two themes; one theme is being pended.
- (4) Application filed for KPT-220 (additional indication for rheumatoid arthritis).
- (5) Introduction of Norspan
- (6) Clinical trial currently being implemented for a multiple number of other domestic themes.

# Progress of the Mid-term Business Plan's Fundamental Policy 2

## Fundamental policy

### 3) Development of Rx products business in US market

- (1) Make sure to obtain approval for HFG-512 (fentanyl; strong analgesic) and FS-67 (salicylate; anti-inflammatory analgesic, and start selling the products. At the same time, accumulate development and application know-how in the US.
- (2) Utmost emphasis will be placed on HKT-500 (ketoprofen; anti-inflammatory analgesic) as the theme for making full-scale inroads into the US market. The theme will be promoted with selected partners.

### 4) Promotion of returns to shareholders

Realize 30% dividend payout ratio in the term ending February 2008



## Progress status

### 3) Development of Rx products business in US market

- (1) FS-67: FDA approval in February 08. HFG-512: Planned approval changed to FY08 because of change in GMP inspection schedule and label changes of advanced products.
- (2) HKT-500: Clinical studies restarted in September 07. Planned filing of application in FY10. Partners are planned to be re-selected.

### 4) Promotion of returns to shareholders

Realized anticipated dividend payout ratio of 30.4% anticipated for Feb. 08

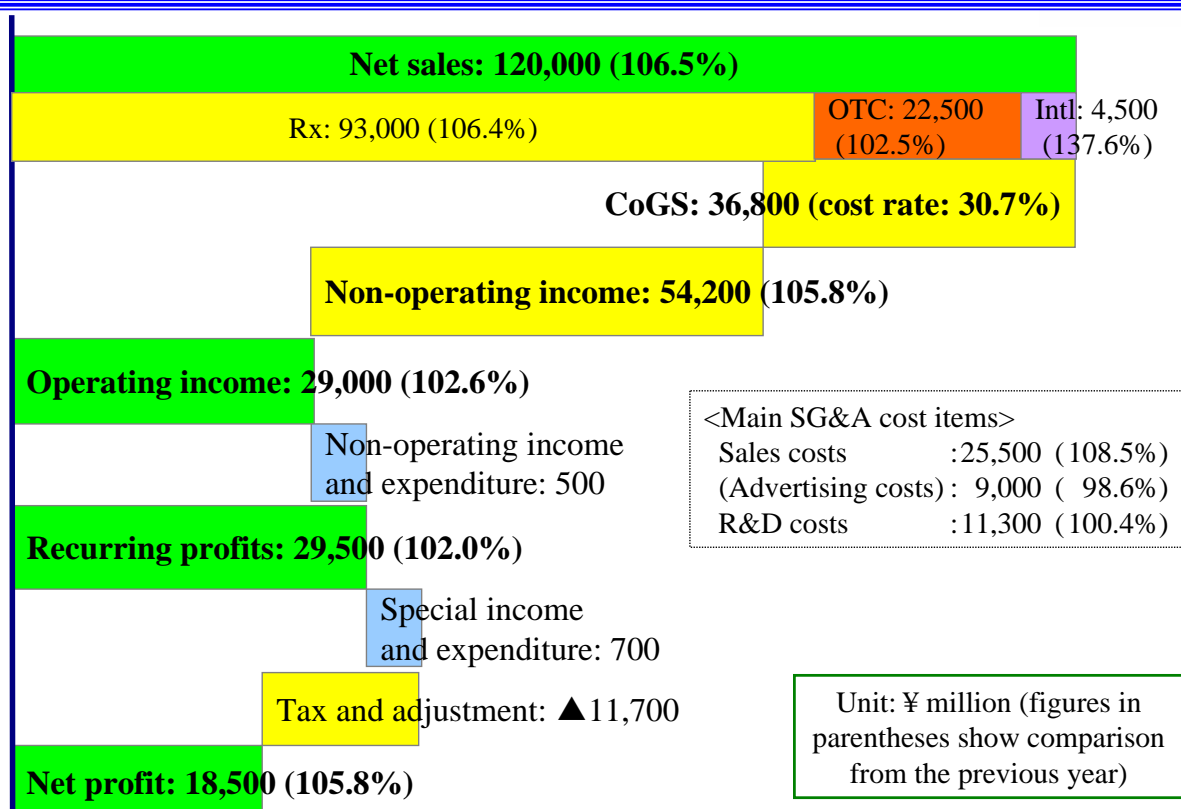
**For the final year of the mid-term business plan, efforts will be focused on not-yet-realized fundamental policy.**

## Outlook of the February 2009 Term (the final year of the mid-term business plan)

Unit: ¥ million (figures in parentheses show comparison from the previous year)

	Consolidated	Non-consolidated	Consolidated-separate ratio
<b>Sales</b>	<b>127,000</b> (106.7%)	<b>120,000</b> (106.5%)	<b>1.06</b>
<b>Operating income</b>	<b>30,000</b> (103.2%)	<b>29,000</b> (102.6%)	<b>1.03</b>
<b>Recurring profits</b>	<b>30,700</b> (101.6%)	<b>29,500</b> (102.0%)	<b>1.04</b>
<b>Net income</b>	<b>19,400</b> (103.9%)	<b>18,500</b> (105.8%)	<b>1.05</b>

## Predictions for Non-consolidated P/L



(Unit: ¥mn)

	FY2/08	YoY change (%)	FY2/09 Target	Targeted YoY increase
Mohrus tape	65,281	+ 16.2%	71,500	+ 9.5%
(Mohrus Tape L)	25,235	+ 35.8%	30,500	+ 20.9%
Mohrus	12,977	△ 3.8%	12,500	△ 3.7%
Naboal	2,073	+ 2.3%	2,000	△ 3.5%
Inside Pap	1,158	△ 12.5%	850	△ 26.6%
Salonpas	6,902	+ 1.5%	7,200	+ 4.3%
Salonsip	4,189	+ 1.8%	4,200	+ 0.3%
Air-Salonpas	1,762	+ 6.2%	1,800	+ 2.2%
Butenalock	2,558	△ 3.0%	2,600	+ 1.6%
Feitas	4,042	+ 8.9%	4,500	+ 11.3%

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## Trend of NSAID market in Japan (Scale by amount)

Unit: mn

	99/08	07/01	08/01	YoY
All nonsteroidal anti-inflammatory drug	245,708	254,838	265,714	+4.3%
<b>Tape preparation</b>	<b>28,708</b>	<b>82,811</b>	<b>94,677</b>	<b>+14.3%</b>
Component ratio	11.7%	32.5%	35.6%	
Gel-patch preparation	79,678	62,325	63,180	+1.4%
Component ratio	32.4%	24.5%	23.8%	
Systemic drug (oral, injection, suppository)	106,807	88,726	90,046	+1.5%
Component ratio	43.5%	34.8%	33.9%	
Other dosage forms (Gel, Cream, etc.)	30,515	20,976	17,811	△15.1%
Component ratio	12.4%	8.2%	6.7%	

Source:IMS JPM

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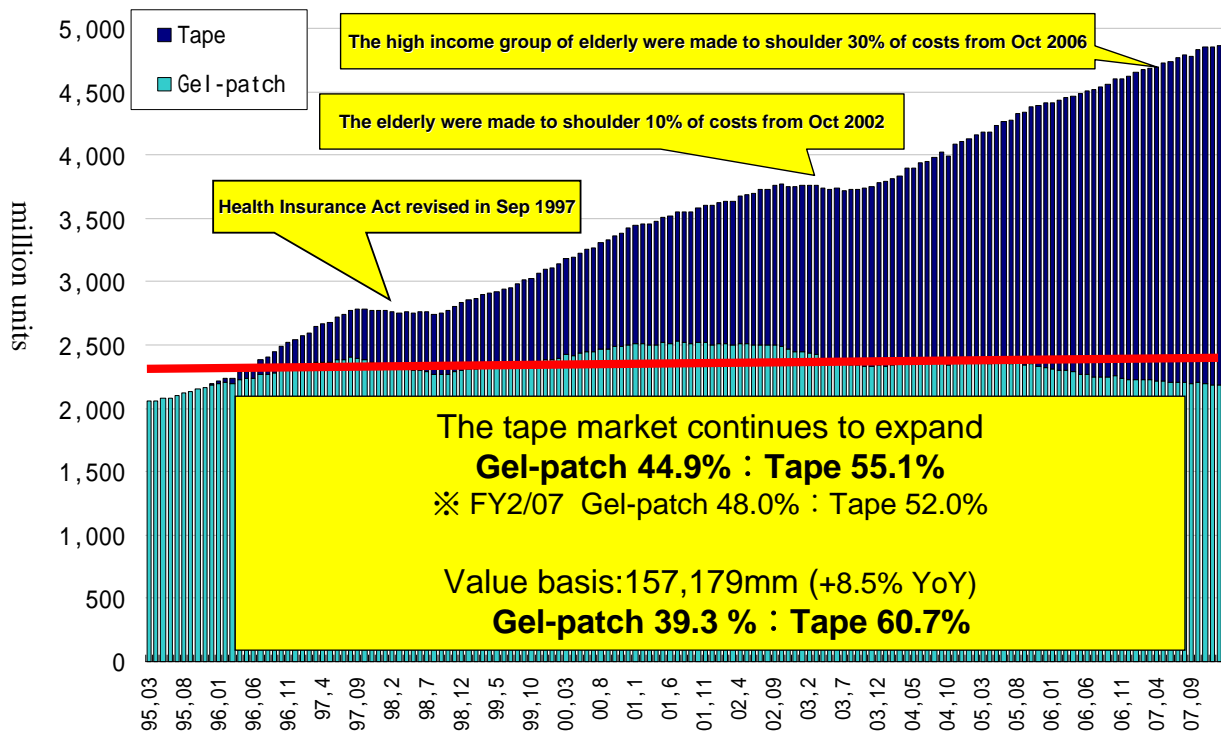
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# The second generation anti-inflammatory analgesic patches market in Japan (Quantity)

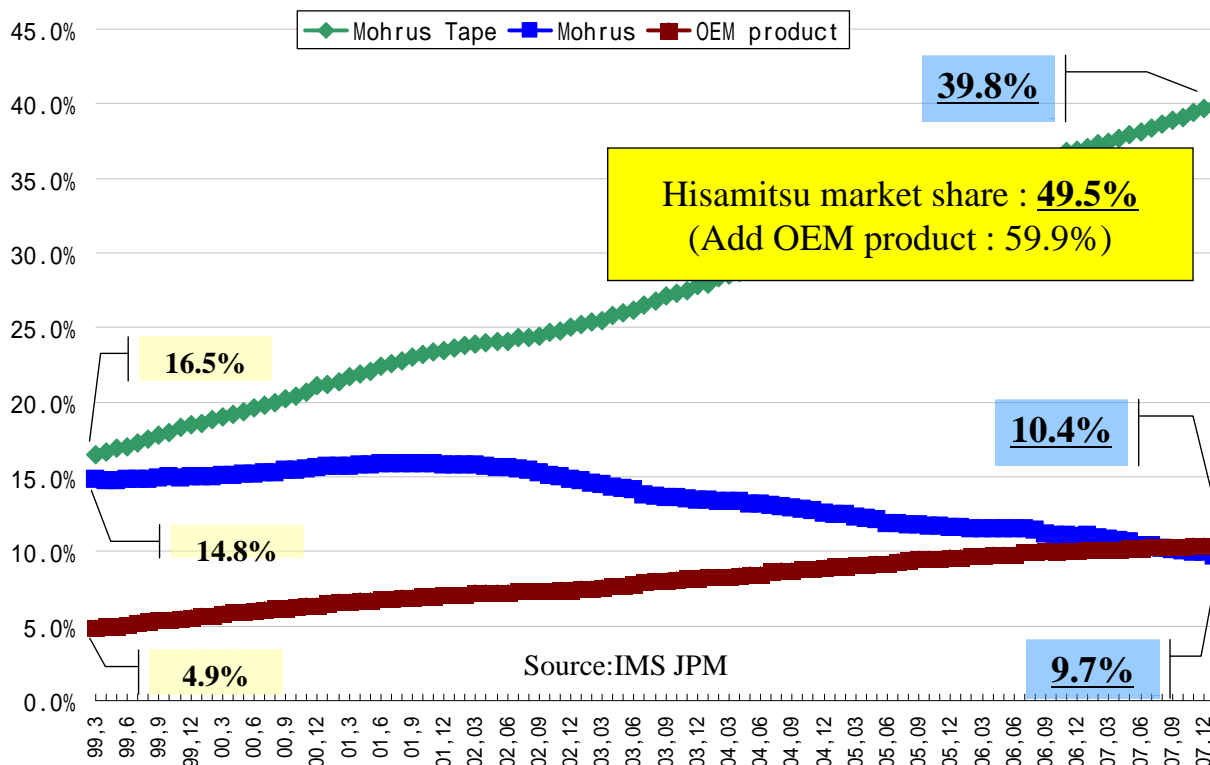
Source:IMS JPM



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# Domestic market share



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# Progress of R&D pipelines

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## R&D Pipeline

Stage	Theme	Generic name	Characteristics	Country	Dosage form	Major indications	Next step
Approval	FS-67 (OTC)	L-menthol Salicylate	FDA-compliant Salonpas	US	Patch	Alleviation of myalgia and joint pain	Planned launch in FY08
Filed	SG-01 (Brand name: Caresheet)	-	Hydrocolloidal product (water absorption properties, adequate moistening environment)	J	Patch	Bedsore, etc. (Medical equipment)	Planned approval in FY08
Filed	HFG-512		Duragesic's GE product	US	TDOS	Alleviation of moderate to severe chronic pain	Planned approval in FY08
Filed	KPT-220	Ketoprofen	Mohrus Tape's additional indication	J	Patch	Relief of pain in rheumatoid arthritis	Planned approval in FY08
Filing being prepared	HFT-290		Drug dosing control by TDOS (once-a-day)	J	TDOS	Alleviation of cancer pain	Filed in FY08
Pill	HKT-500	Ketoprofen	US version of Mohrus Tape	US	Patch	Alleviation of joint pain, low back pain and myalgia	Filed in FY10
Pill	Norspan (obtained exclusive sales rights in Japan from Mundipharma K.K.)	Buprenorphine	Pain control for which no analgesic effects can be obtained by NSAIDs treatment	J	TDOS	Alleviation of non-cancer pain	Filed in FY08

\* The portions indicated in yellow show those with changes from the previous announcement made on December 27.

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## **FS-67 (US: Alleviation of myalgia and joint pain)**

- FDA approval obtained in February 08. Planned to be released under two brand names.
  - Salonpas® Pain Relief Patch
  - Salonpas® Arthritis Pain
- Pediatric clinical test is being planned as a postmarketing clinical study.

## **HFG-512 (US: Alleviation of moderate to severe chronic pain)**

- Inquiry items from the FDA during GMP inspection have already been answered.
- Along with changes in the label of advanced products, re-manufacturing is planned by obtaining new packaging materials.
- Planned approval in FY08.

## **KPT-220 (Japan: Alleviation of pain in rheumatoid arthritis)**

- Application filed in September 07.
- Anticipated to be approved in FY08.

## **HFT-290 (Japan: Alleviation of cancer pain; once daily)**

- PIII study was completed in October 07, and application documents are currently being prepared.
- Application planned to be filed in FY08.

## **HKT-500 (US: Alleviation of joint pain, low back pain and myalgia)**

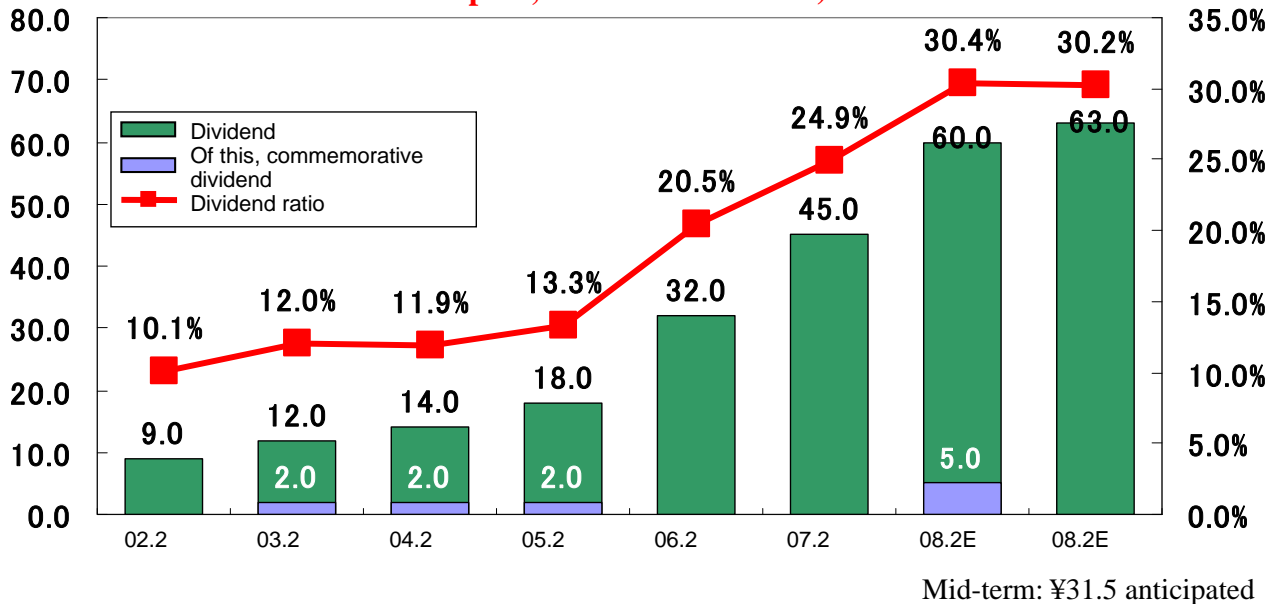
- PIII is currently being implemented.

## **Norspan (Japan: Alleviation of non-cancer pain)**

- PIII study was completed in December 07.
- Application planned to be filed in FY08.

# Changes in Dividend per Share

➤ For the February 09 period, a commemorative dividend of 5 yen, expected for February 2008, will be incorporated in the regular dividend, for an increased dividend of 3 yen, and a 30.2% dividend payout ratio is predicted. (The 30% dividend payout ratio, which is the goal of the midterm business plan, will be maintained.)



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

Apr 8th, 2008

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