# Account settlement for February 2009 term and future outlook

This presentation material includes the future outlook. The views and outlook were formulated, based on in-house and other materials that are believed to be trustworthy. However, they do not guarantee future business performances. Note, therefore, that the actual sales, profits and other results may differ from the content featured in this material.

Hisamitsu Pharmaceutical Co., Inc. April 7, 2009

Conveying the benefits of adhesive patch treatments

**Hisamitsu** 

## **Business performance for period ended February 2009**

#### **Alisamitsu**

#### **Consolidated PL**

Sales: 124,655 (104.7%)

Sales cost: 39,884 (110.5%)

Sales administrative fees: 52,239 (96.9%)

**Operating profit: 32,532 (111.9%)** 

Non-operating revenue and expenditure: ▲56

**Ordinary profit: 32,476 (107.5%)** 

Other revenue and expenditure: ▲268

Corporate tax, etc. and adjustment amount: ▲ 13,087

**Current net profit: 19,120 (102.4%)** 

Unit: ¥1 million

(Figures in parentheses show year-on-year changes)

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#### **Non-consolidated PL**

**Alisamitsu** 

Sales: 118,142 (104.9%)

**Prescription drugs:** 92,776 (106.1%)

OTC: International: 21,668 (98.7%) 3,699 (113.1%)

Sales cost: 36,906 (111.4%)

Sales administrative fee: 49,342 (96.3%)

**Operating profit:** 31,893 (112.8%)

<Primary sales administrative fees> Sales: 22,344 (95.4%)

Non-operating revenue and expenditure: 284

(Advertising) 8,613 (94.3%)

**Ordinary profit: 3**2,177 (111.3%)

R&D: 9,609 (85.4%)

Other revenue and expenditure: ▲112

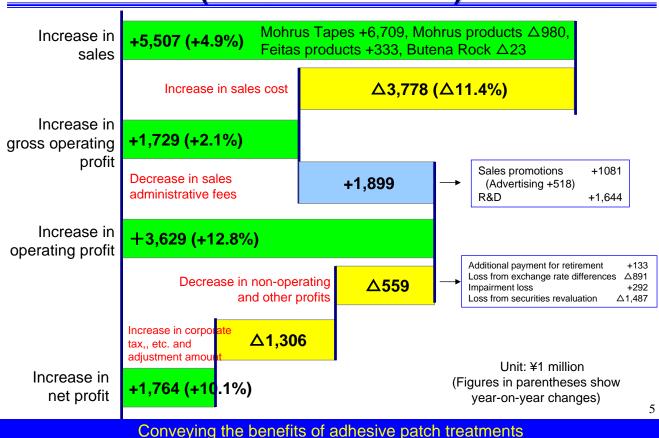
Corporate tax, etc. and adjustment amount: ▲12,813

Current net profit: 19,251 (110.1%)

(Figures in parentheses show year-on-year changes)

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## Summary of profit-loss (non-consolidated)



### Sales results of major products disamitsu

Unit: ¥1 million

		Feb. '08 term	Year-on-year	Feb. '09 term	Year-on-year
Ethical drugs	Mohrus Tapes	65,281	116.2%	71,897	110.1%
	Mohrus Paps	12,977	96.2%	11,996	92.4%
thica	Naboal products	2,073	102.3%	2,004	96.7%
Ш	Inside Pap	1,158	87.5%	954	82.4%
	Salonpas products	6,902	101.5%	7,053	102.2%
OTC drugs	Salonship products	4,189	101.8%	3,927	93.7%
	Air Salonpas products	1,762	106.2%	2,026	115.0%
	Butena rock products	2,558	97.0%	2,534	99.1%
	Feitas products	4,042	108.9%	4,375	108.2%

## Outlook for period ending February 2010

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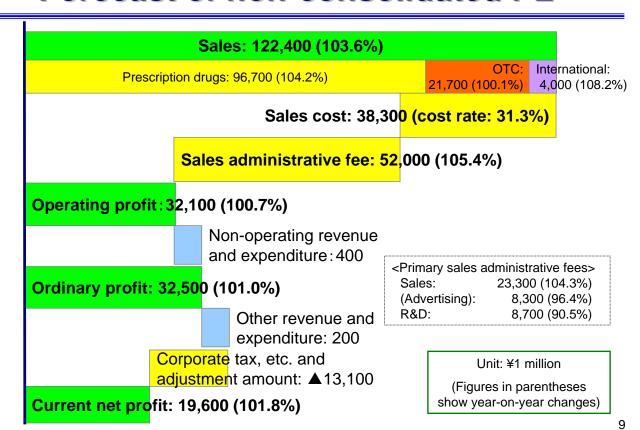
## **Business forecast for the term ending February 2010**

**Alisamitsu** 

Unit: ¥1 million (Figures in parentheses show year-on-year changes)

	Consolidated		Consolidated/non- consolidated ratio	
Sales	128,600	122,400	1.05	
	(103.2%)	(103.6%)		
Operating	32,800	32,100	1.02	
profit	(100.8%)	(100.6%)		
Ordinary profit	33,100	32,500	1.02	
	(101.9%)	(101.0%)		
Current net	19,800	19,600	1.01	
profit	(103.6%)	(101.8%)		

#### Forecast of non-consolidated PL Islamitsu



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### Sales plans for the main products samutsu

Unit: ¥1 million

		Feb. '09 term	Year-on-year	Feb. '10 (Expected)	Year-on-year
Ethical drugs	Mohrus Tapes	71,897	110.1%	76,350	106.2%
	Mohrus Paps	11,996	92.4%	11,200	93.4%
hica	Naboal products	2,004	96.7%	2,000	99.8%
Ξ	Inside Pap	954	82.4%	800	83.9%
OTC drugs	Salonpas products	7,053	102.2%	7,200	102.1%
	Salonship products	3,927	93.7%	3,450	87.9%
	Air Salonpas products	2,026	115.0%	1,900	93.8%
	Butena rock products	2,534	99.1%	2,100	82.9%
	Feitas products	4,375	108.2%	5,200	118.9%

#### 10-year trends of Japan's non-steroidal anti-inflammatory Alisamitsu analgesic market (based on NHI drug price amounts)

Unit: ¥1 million

	December '9		December '99	December '08		10-year growth rate	10-year growth rate, average
Total ethical drug market		ethical drug market	6,427,719	8,254,290		128.4%	102.8%
Non-steroidal anti- inflammatory analgesics			253,587	274,518		108.3%	100.9%
Systemic anti-inflammatory analgesics (oral, injections, suppositories)		analgesics	108,407	91,709		84.6%	98.2%
	Component ratio		42.7%	33.4%			
а	Localized anti-inflammatory analgesic (external application)		145,180	182,809		125.9%	102.6%
	Component ratio		57.3%	66.6%			
	7	Second-generation tape products	31,715	103,695		327.0%	114.1%
ءِ 🛚		Component ratio	12.5%	37.8%			
Breakdown		Second-generation adhesive skin patches	81,321	59,835		73.6%	96.6%
eak		Component ratio	32.1%	21.8%			
Ŗ		Other local preparations (gels, creams, etc.)	32,144	19,279		60.0%	94.5%
		Component ratio	12.7%	7.0%			

<sup>\*</sup>Second generation: Types that contain NSAI ingredients

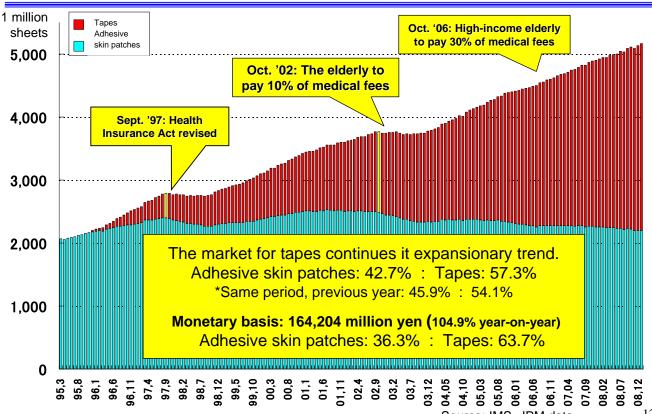
Source: IMS, JPM data

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#### Trends of second-generation adhesive skin patch market (volume-basis)

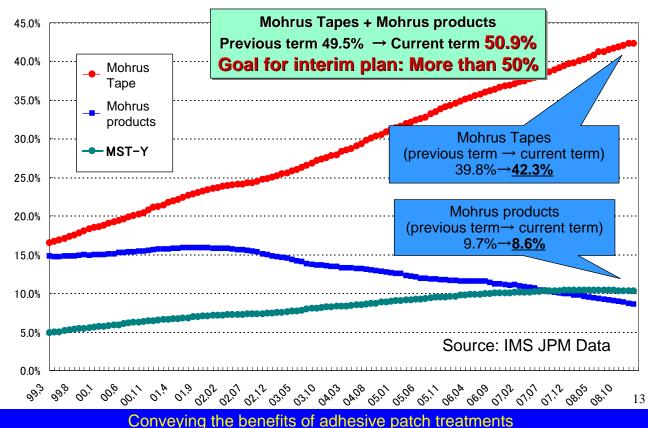




Source: IMS, JPM data

#### Changes in shares of second-generation Alisamitsu adhesive skin patches





**Alisamitsu** 

### **Progress of R&D pipelines**

Stage	Theme	Target	Dosage form	Characteristics	Next step
Application being filed	SG-01	Japan	Adhesive skin patch	Bedsores, etc. (medical device)	Approval expected in FY'09
Application being filed	HFT-290 (Co-marketed with Kyowa Hakko Kirin)	Japan	Adhesive skin patch	Alleviation of cancerous pain	Approval expected in FY'09
Application being filed	BTDS (Introduced from Mundipharma K.K.)	Japan	Adhesive skin patch	Alleviation of non-cancerous pain	Approval expected in FY'10
Application being filed	KPT-220	Japan	Adhesive skin patch	Easing of pain due to rheumatoid arthritis	Approval expected in FY'10
Application being filed	HFG-512	US	Adhesive skin patch	Alleviation of moderate to severe chronic pain	Undisclosed
P III	HKT-500	US	Adhesive skin patch	Alleviation of joint pain, lower back pain and muscle pain	Currently being adjusted
PΙΙ	HTU-520	Japan	Adhesive skin patch	Nail tinea	Phase III in FY'10
PΙΙ	HOB-294	Japan	Adhesive skin patch	Hyperactive bladder	Phase III in FY'10

<sup>\*</sup>Sections shown in yellow indicate those that changed from the previous announcement made on Dec. 27.

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#### **Clinical trial progress status**



#### HKT-500 (US: arthralgia, lower back pain, muscle pain)

#### [Current status]

• The FDA is demanding statistically significant differences in multiple sites in a comparative test with a placebo.

#### <Results of clinical tests>

- Knee ⇒ No statistically significant differences were seen.
- Ankle ⇒ No statistically significant differences were seen.
- Shoulder ⇒ Statistically significant differences were shown.

#### [Future actions]

 Additional tests are being planned, and the details are currently being studied.

#### Clinical trial progress status



#### HFT-290 (Japan: cancerous pain)

- Application filed in June 2008.
- Approval expected to be obtained in FY2009.

#### BTDS (Japan: non-cancerous pain)

- Application filed in October 2008. (Mundipharma K.K.)
- Approval expected to be obtained in FY2010.

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

- Application filed in September 2007.
- Approval expected to be obtained in FY2010.

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

- Application filed in June 2005.
- Period of approval is undisclosed (because of measures to counter generic competition).

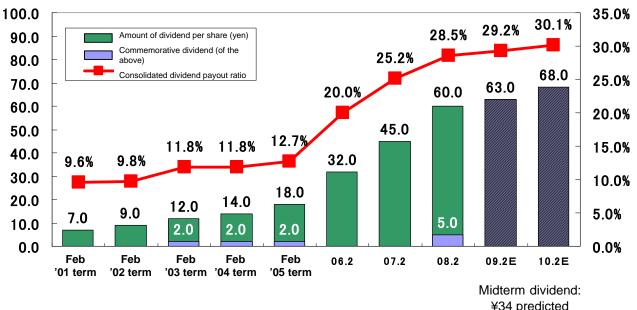
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#### Forecast of dividends

**Alisamitsu** 

> For the term ending February 2010, the dividend payout is predicted to be ¥68, or ¥5 more than the amount forecasted for the term ended February 2009. Dividend payout ratio is expected to be 30.1% (consolidated basis).



¥34 predicted

## Aiming at enhancing the QOL of people around the world

Explanation Meeting for the February 2009 Term Account Settlement

April 7, 2009

Hisamitsu Pharmaceutical Co., Inc.

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