# Hisamitsu Pharmaceutical Co., Inc. Q1 FY02/2014 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.

## Hisamitsu Pharmaceutical Co., Inc. Jul. 10<sup>th</sup>, 2013

Patch and Care of People around the World

**Alisamitsu** 

#### **Consolidated PL**

Unit:¥ million

	Q1 FY02/13	Q1 FY02/14	YoY	Consolidated / Non-consolidated
Net sales	34,670	37,065	+6.9%	1.20
CoGS	12,532	13,841	+10.4%	
as a % of sales	36.1%	37.3%		
SG&A costs	16,825	18,152	+7.9%	
Advertising costs	3,093	3,428	+10.8%	
R&D spending	3,423	3,106	-9.3%	
Operating profits	5,313	5,071	-4.6%	0.75
Recurring profits	6,621	6,720	+1.5%	0.95
Net profits	3,613	7,514	+108.0%	0.96

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### **Summary of Profit and Loss**

Unit:¥ million

	① Q1 FY02/13	② Q1 FY02/14	2-1	Main factor
Net sales	34,670	37,065	+2,395	
Rx Business	24,659	23,485	-1,174	•[Last year] Increase in sales of most products as a reaction, before National Health Insurance price reduction.
OTC Business	3,790	5,887	+2,097	•Increase in sales of a new product and major products.
Intl Business	1,021	1,474	+453	•Increase in sales of major products.
Noven	3,223	3,868	+645	Influence of the exchange. Increase in sales of major products
Others	1,977	2,351	+374	•Increase in sales of overseas subsidiaries.
CoGS	12,532	13,841	+1,309	•Increase in Net sales.
as a % of sales	36.1%	37.3%	+1.2%	•Change of sales structure.
SG&A costs	16,825	18,152	+1,327	•Increase in SG&A costs of Noven.
Operating profits	5,313	5,071	-242	
Non-operating balance	1,308	1,648	+340	•Foreign exchange gain.
Recurring profits	6,621	6,720	+99	
Extraordinary balance	-389	5,082	+5,471	•License fee (Distribution agreement).
Net profits	3,613	7,514	+3,901	

2

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### Non-consolidated PL

<u>Unit:¥ mil</u>lion

	Q1 FY02/13	Q1 FY02/14	YoY
Net sales	29,470	30,848	+4.7%
Rx Business	24,659	23,485	-4.8%
OTC Business	3,790	5,887	+55.3%
Intl Business	1,021	1,474	+44.4%
CoGS	9,687	10,591	+9.3%
as a % of sales	32.9%	34.3%	
SG&A costs	13,829	13,469	-2.6%
Advertising costs	2,895	2,710	-6.4%
R&D spending	2,639	2,216	-16.0%
Operating profits	5,954	6,786	+14.0%
Recurring profits	6,065	7,149	+17.9%
Net profits	3,408	7,798	+128.8%

3

#### **Noven PL**

	Unit: ¥ million			Unit:	\$ thousand	
	Q1 FY02/13	Q1 FY02/14	YoY	Q1 FY02/13	Q1 FY02/14	YoY
Net sales	3,223	3,868	+20.0%	40,416	41,795	+3.4%
Daytrana	1,356	1,665	+22.8%	17,012	17,987	+5.7%
Vivelle-dot	1,071	1,204	+12.4%	13,439	13,010	-3.2%
Minivelle	-	178	-	-	1,923	-
Noven Therapeutics	418	370	-11.5%	5,249	4,005	-23.7%
Others	378	451	+19.3%	4,716	4,870	+3.3%
CoGS	1,842	2,073	+12.5%	23,107	22,396	-3.1%
as a % of sales	57.2%	53.6%		57.2%	53.6%	
SG&A costs	2,031	3,575	+76.0%	25,467	38,626	+51.7%
R&D spending	687	893	+30.0%	8,622	9,650	+11.9%
Others	1,343	2,682	+99.7%	16,845	28,976	+72.0%
Operating profits	-650	-1,779	_	-8,159	-19,227	-
Nonoperating balance	1,244	1,582	+27.2%	15,608	17,097	+9.5%
Equity in earnings of Novogyne	1,649	2,278	+38.1%	20,686	24,614	+19.0%
Amortization of fair value adjustment to investment in Novogyne	-407	-826	_	-5,111	-8,927	_
Recurring profits	594	-197	_	7,449	-2,130	-
Net profits	445	86	-80.7%	5,586	930	-83.4%
Exchange rate (¥/USD)	¥79.75	¥92.57				

\*Noven Therapeutics: Pexeva, Lithobid, Stavzor

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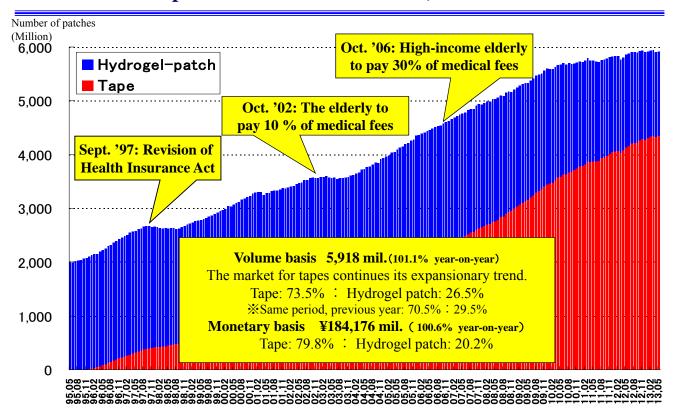
### Sales results of major products

Unit:¥ million

		Q1	Q1	
		FY02/13	FY02/14	YoY
	Mohrus Tape	19,515	18,515	-5.1%
	Mohrus Pap	2,038	1,726	-15.3%
	Fentos Tape	883	836	-5.3%
ıgs	Norspan Tape	257	439	+70.8%
늄	Naboal	391	373	-4.6%
Ethical drugs	Estrana Tape	316	318	+0.6%
:thi	Daytrana	1,356	1,665	+22.8%
"	Vivelle-Dot	1,071	1,204	+12.4%
	Minivelle	-	178	_
	Noven Therapeutics	418	370	-11.5%
	Salonpas products	1,113	1,491	+34.0%
gs	Allegra FX	-	1,183	_
OTC drugs	Butenalock products	816	1,112	+36.3%
	Salonship products	655	873	+33.3%
Ö	Feitas products	599	771	+28.7%
	Air Salonpas products	441	420	-4.8%

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### Trends of second-generation non-steroidal anti-inflammatory disamitsu patch market (volume-basis)

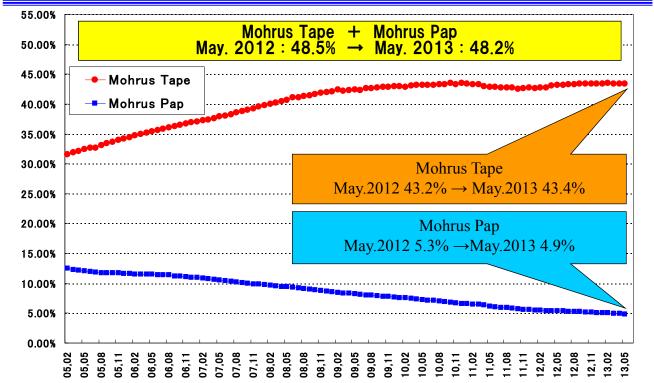


Source: IMS, JPM data (~May. 2013) \*No reproduction or republication without written permission.

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### Changes in shares of second-generation non-steroidal anti-inflammatory patch





Notice: The constitution items have been re-defined in these data. Therefore share numerical value has been changed in comparison with data shown previously.

Source: IMS, JPM data (~May. 2013) \*No reproduction or republication without written permission.



#### NEOXY®TAPE73. 5mg:Outline



■Date of launch in Japan: June 27, 2013

■Administration :Once a day

■NHI drug price:189.40 yen/sheet

■Distributed by: Hisamitsu Pharmaceutical Co., Inc.

& Asahi Kasei Pharma Corp.

■Main Feature:

• Transdermal overactive bladder treatment medication.

•Effect at the same level of existing oral anticholinergic drugs.

•Reduction of side effects of dry mouth and constipation.



59.9mm

#### Available for more patients.

- The patient whose side effect developed in with oral medication.
- The patient having difficulty in ingestion. ...etc

8

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### **R&D** Pipeline

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Stage	Theme	Target	Dosage form	Characteristics	Next step
Approval	Brisdelle (LDMP)	USA	Oral	Vasomotor symptoms (Hot flashes)	Planned Launch in Nov. 2013
Filed (ANDA)	HP-1010	USA	Adhesive skin patch	Relief of pain associated with post-herpetic neuralgia	No disclosure
Filed (ANDA)	HP-1030	USA	Adhesive skin patch	Alzheimer's disease	No disclosure
Application being prepared	HFT-290 (Additional Indication of FENTOS Tape)	JPN	Adhesive skin patch	Relief of non-malignant chronic pain	To be filed in FY13
Phase2	ATS	USA	Adhesive skin patch	Attention Deficit Hyperactivity Disorder (ADHD)	Phase3 in FY13
Phase2	HP-3000	JPN	Adhesive skin patch	Parkinson's disease	Phase3 in FY15
Phase2	HP-3060	JPN	Adhesive skin patch	Allergic rhinitis	Phase3 in FY14

**XYellow-highlighted parts are changes from the previous announcement made on Apr.11th, 2013** 

#### Brisdelle™: Outline

#### **■**Feature

The first and only FDA-approved nonhormonal option for the treatment of moderate to severe VMS associated with menopause.

#### **■**Sales and Marketing

Noven will launch in November 2013, in the U.S. through Noven Therapeutics Women's Health Unit. Noven will provide resources (DTC and sponsoring medical education programs,...etc) to educate health care prividers and patients about Brisdelle.

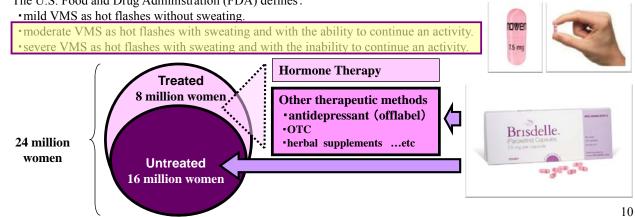
#### **■** Dosage and Administration

The low dose of 7.5mg as a capsule of paroxetine as a mesylate salt taken once daily at bedtime.

#### ■Indication

BRISDELLE<sup>TM</sup> (Paroxetine) Capsules is a prescription medicine used to reduce moderate to severe hot flashes associated with menopause.

The U.S. Food and Drug Administration (FDA) defines:



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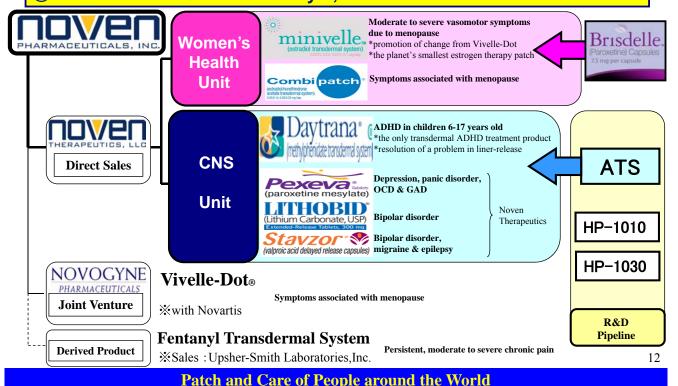
### Noven 1: Outline





### Noven2: Recent trends and major products

1 Newly established of Women's Health Unit. (moved sales from JV.)2 Minivelle launched on January 2, 2013.



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# Aiming at improving the QOL of people around the world

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Hisamitsu Pharmaceutical Co., Inc.