# Hisamitsu Pharmaceutical Co., Inc.

This presentation material contains information that constitutes forwardlooking 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.

**Q3 FY02/2019 Results** 

## Hisamitsu Pharmaceutical Co., Inc. Jan. 11<sup>th</sup>, 2019

Promoting Patch Treatment Culture Worldwide

Agenda

1. Looking back on the Q3 FY02/2019

## 2. Summary of Financial Results for Q3 FY02/2019

- 3. Consolidated PL
- 4. Non Consolidated PL
- 5. Noven PL
- 6. Sales results by product
- 7. Trends of 2nd-generation non-steroidal anti-inflammatory patch in Japan
- 8. R&D Pipeline

Additional data

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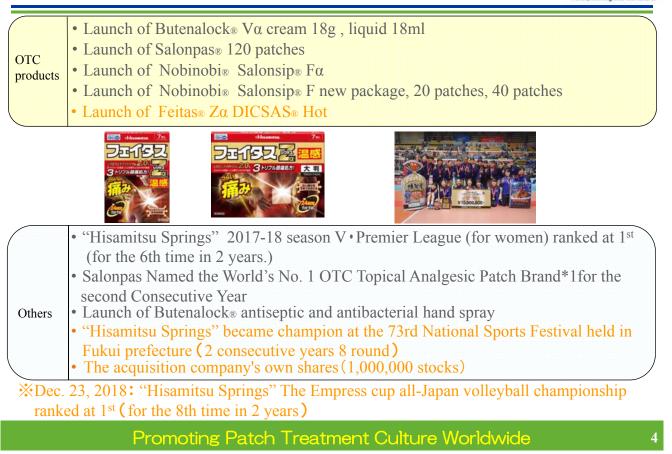
## 1. Looking back on the Q3 FY02/2019 (1)

Ethical products	<ul> <li>Launch of Allesaga® Tape 4mg, 8mg (Transdermal, Allergic rhinitis treatment patch)</li> <li>Noven announces successful resolution of FDA warning letter</li> <li>Approval of supplemental new drug application (NDA) for the addition of a new 0.5 mg dose of the transdermal, pain management patch FENTOS® TAPE (development code: HFT-290)</li> <li>HP-3000 (a transdermal drug for treating Parkinson's disease) Application for manufacturing and marketing approval</li> <li>HP-5070 (a transdermal drug for the treatment of primary local hyperhidrosis) Commencement of Phase II Clinical Study in Japan</li> <li>Approval for manufacturing and marketing approval of OABLOK®PATCH in Taiwan (Transdermal, Overactive bladder treatment patch)</li> <li>Listing on the NHI drug price standard and marketing of a new dose 0.5 mg of Fentos® Tape (Development code: HFT-290), Transdermal, Pain management patch</li> </ul>
TAI *Dec the *Dec	<ul> <li>e. 11, 2018: The Sales transfer of the transdermal, pain management patch NORSPAN®</li> <li>PE</li> <li>e. 14, 2018: Completion of Phase III clinical study in opioid analgesic naïve patients of transdermal, pain management patch FENTOS®TAPE (development code:HFT-290)</li> <li>e. 17, 2018: A new drug application for HP-3070(Transdermal Patch for the Treatment Schizophrenia) in the U.S.</li> </ul>

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## 1. Looking back on the Q3 FY02/2019 (2)

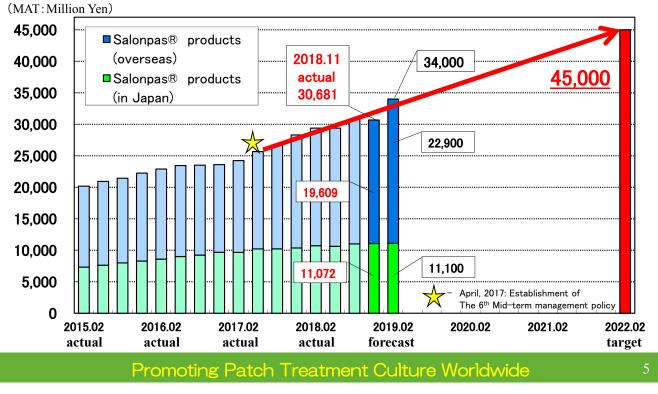
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## 1. Looking back on the Q3 FY02/2019 (3)



### Sales transition of Salonpas® products> Target: annual sales of 45 billion yen(at FY02/22)



## 1. Looking back on the Q3 FY02/2019 (4)

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### About the Sales of Salonpas®

- Salonpas® has been acknowledged as World's No.1 OTC Topical Analgesics Patch Brand for the second consecutive year on May 18, 2018.
  - $\Rightarrow$  Along with this, we needed to change the packages of Salonpas® in US, because the "WORLD'S BRAND No.1" logos were inserted in the Salonpas® packages.
  - $\Rightarrow$  We stopped the exportation temporarily and changed the packages.



## 2. Summary of Financial Results for Q3 FY02/2019站 (大来へ)

## **Consolidated**

Unit:¥ million

	Q3 FY02/2019	FY02	/2019	
	Actual	Forecast	Progress rate	
Net sales	102,574	148,500	69.1%	
Operating profits	15,941	24,000	66.4%	
Recurring profits	17,412	26,300	66.2%	
Net profits	13,329	19,200	69.4%	

XNo change is made on forecast.

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## 3. Consolidated PL (1) - Comparison with the previous period performance - 貼るを、未来 - Patch. moving into the full

Unit:¥ million

	Actual performance for FY02/18 (Q3)	Actual performance for FY02/19 (Q3)	Change	Percentage Change
Net sales	109,553	102,574	-6,978	-6.4%
C₀GS	40,267	38,175	-2,092	-5.2%
as a % of sales	36.8%	37.2%		
SG&A costs	48,598	48,458	-140	-0.3%
Sales promotion costs	9,364	10,155	+790	+8.4%
Advertising costs	8,162	9,399	+1,237	+15.2%
R&D spending	11,561	9,369	-2,192	-19.0%
Others	19,510	19,533	+23	+0.1%
Operating profits	20,687	15,941	-4,746	-22.9%
Recurring profits	22,043	17,412	-4,631	-21.0%
Net profits	15,840	13,329	-2,510	-15.8%

### 3. Consolidated PL (2) - Summary of Profit and Loss -

### Unit:¥ million

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	Actual performance for FY02/18 (Q3)	Actual performance for FY02/19 (Q3)	Change	Main factor
Net sales	109,553	102,574	-6,978	
Hisamitsu (Non consolidated)	83,540	78,519	-5,021	•Decrease in sales of Rx Business. •Increase in sales of OTC/Intl Business.
Noven	15,193	13,675	-1,518	•Decrease in sales of major products.
Others *	10,820	10,380	-440	
CoGS	40,267	38,175	-2,092	•Decrease in sales
as a % of sales	36.8%	37.2%	H	
SG&A costs	48,598	48,458	-140	
Operating profits	20,687	15,941	-4,746	
Non-operating balance	1,356	1,470	+114	
Recurring profits	22,043	17,412	-4,631	
Extraordinary balance	481	209	-271	
Net profits	15,840	13,329	-2,510	
				* "Others" in studes serves lideted a directory

\* "Others" includes consolidated adjustment.

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## 4. Non Consolidated PL - Comparison with the previous period performance - 貼るを、未来へ。 Patch, moving into the future.

Unit:¥	million

				Uni
	Actual performance for FY02/18 (Q3)	Actual performance for FY02/19 (Q3)	Change	Percentage Change
Net sales	83,540	78,519	-5,021	-6.0%
Rx Business	55,581	49,345	-6,236	-11.2%
OTC Business	19,875	20,579	+704	+3.5%
Intl Business	8,083	8,594	+511	+6.3%
CoGS	29,040	28,536	-504	-1.7%
as a % of sales	34.8%	36.3%		
SG&A costs	38,561	37,298	-1,263	-3.3%
Sales promotion costs	7,691	7,937	+246	+3.2%
Advertising costs	6,138	6,889	+750	+12.2%
R&D spending	9,355	7,429	-1,926	-20.6%
Others	15,375	15,041	-334	-2.2%
Operating profits	15,937	12,683	-3,253	-20.4%
Recurring profits	16,863	13,979	-2,883	-17.1%
Net profits	12,377	10,816	-1,561	-12.6%

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## 5. Noven PL - Comparison with the previous period performance -

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	Actual performance for FY02/18 (Q3)	Actual performance for FY02/19 (Q3)	Change	Percentage Change			
Net sales <sup>*</sup>	15,193	13,675	-1,518	-10.0%			
CoGS	7,933	6,784	-1,148	-14.5%			
as a % of sales	52.2%	49.6%					
SG&A costs	4,943	5,054	+110	+2.2%			
Sales promotion costs	223	278	+54	+24.3%			
Advertising costs	58	195	+137	+234.9%			
R&D spending	2,163	1,950	-212	-9.8%			
Others	2,497	2,629	+132	+5.3%			
Operating profits	2,316	1,835	-480	-20.7%			
Nonoperating balance	773	199	-573				
Pretax profits	3,089	2,030	-1,058	-34.3%			
Net profits	2,316	1,644	-671	-29.0%			
			* Results be	fores			
Exchange rate (¥/USD)	¥111.81	¥109.66		etore ed adjustment.			

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6. Sales results by product (1) - Rx Business -

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### Unit:¥ million

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	Actual performance for FY02/19 (Q3)				Change			Percentage Change		
	Total	Japan	Overseas	Total	Japan	Overseas	Total	Japan	Overseas	
Rx Business	63,285	49,345	13,939	-7,960	-6,236	-1,724	-11.2%	-11.2%	-11.0%	
$Fentos_{\scriptscriptstyle (\!$	3,897	3,897	_	+191	+191	-	+5.2%	+5.2%	-	
Norspan <sub>®</sub> Tape	1,496	1,496	_	-64	-64	-	-4.1%	-4.1%	-	
Neoxy <sub>®</sub> Tape	514	514	_	-103	-103	-	-16.7%	-16.7%	_	
Abstral <sup>®</sup>	156	156	-	-8	-8	-	-4.9%	-4.9%	-	
Allesaga <sub>®</sub> Tape	109	109	_	+109	+109	-	-	-	_	
Mohrus <sub>®</sub> Tape	31,586	31,548	37	-5,997	-5,937	-60	-16.0%	-15.8%	-61.9%	
Mohrus <sub>®</sub> Pap	5,674	5,674	_	-714	-714	-	-11.2%	-11.2%	-	
(Mohrus <sub>®</sub> Pap XR)	4,063	4,063	_	-134	-134	-	-3.2%	-3.2%	_	
Others	6,581	5,949	631	+235	+291	-57	+3.7%	+5.1%	-8.3%	
Minivelle <sup>®</sup>	4,851	-	4,851	-986	_	-986	-16.9%	-	-16.9%	
Vivelle-Dot <sup>®</sup> prodcts	3,298	-	3,298	-193	_	-193	-5.5%	-	-5.5%	
CombiPatch <sup>®</sup> prodcts	3,289	-	3,289	+291	-	+291	+9.7%	-	+9.7%	
Brisdelle®	0	-	0	+10		+10	-	-	_	
Daytrana®	1,830		1,830	-617		-617	-25.2%	-	-25.2%	
Others of Noven products	0	-	0	-112	_	-112	-	-	-	

## 6. Sales results by product (2) - OTC Business -

## Unit:¥ million

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	Actual performance for FY02/19 (Q3)			Change			Percentage Change		
	Total	Japan	Overseas	Total	Japan	Overseas	Total	Japan	Overseas
OTC Business	36,707	20,579	16,127	+940	+704	+236	+2.6%	+3.5%	+1.5%
Salonpas <sub>®</sub> products	22,737	8,738	13,999	+1,290	+353	+938	+6.0%	+4.2%	+7.2%
Salonsip <sub>®</sub> products	2,568	1,762	805	-934	-795	-139	-26.7%	-31.1%	-14.7%
$Air_{\scriptscriptstyle{ extsf{R}}}$ Salonpas $_{\scriptscriptstyle{ extsf{R}}}$ products	1,411	912	498	+31	+34	-3	+2.2%	+3.9%	-0.6%
Feitas <sub>®</sub> products	4,526	4,526	-	+471	+471	-	+11.6%	+11.6%	-
Butenalock <sub>®</sub> products	1,401	1,401	-	+35	+35	-	+2.6%	+2.6%	-
Allegra <sup>®</sup> FX	1,681	1,681	-	+389	+389	-	+30.1%	+30.1%	-
Others	2,379	1,555	824	-343	+217	-559	-12.6%	+16.2%	-40.4%

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## 7. Trends of second-generation non-steroidal anti-inflammatory patch in Japan (1)

Number of patches (Million) 6,000 Market trends on volume basis **Oct.'06: High-income elderly** Hydrogel Patch to pay 30% of medical fees Tape 5,000 **Oct.'02:The elderly to** pay 10% of medical fees Apr.'16: "70 sheets per prescription" limit 4,000 Sept.'97: Revision of **Health Insurance Act** 3.000 2.000 Proportion Nov.2018(MAT) YoY Hydrogel Tape Patch 1,000 Volume Basis 5,216 (million) 96.8% 82.9% 17.1% 92.3% 85.2% **Monetary Basis** ¥138,047 (million) 14.8% 0 96,11 97,05 97,11 98,05 98,05 98,11 99,11 00,05 00,11 01,05 01,11 06,05 06,11 07,05 07,11 08,05 08,01 08,01 08,11 09,05 11,05 11,05 11,05 

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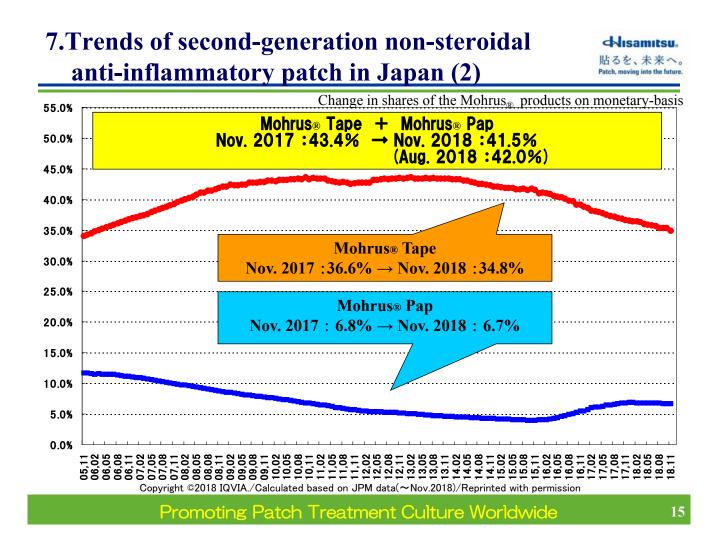
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## 8. R&D Pipeline

	Stage	Theme	Target	Dosage Form	Characteristics	Next Step
1	Filed (ANDA)	HP-1010	USA	Patch	Relief of pain associated with post-herpetic neuralgia	No disclosure
2	Filed	HP-3000	JPN	Patch	Parkinson's disease	To be approved in FY19
3	Filed	HP-3070	USA	Patch	Schizophrenia	To be approved in FY19
4	Filed being prepared	HFT-290 (opioid analgesic na ï ve patients)	JPN	Patch	Cancer pain	To be filed in FY19
5	Phase3	HP-3150	JPN	Patch	Cancer pain	To be filed in FY20
6	Phase3 being prepared	ATS	USA	Patch	Attention Deficit Hyperactivity Disorder (ADHD)	Phase3 start in FY18
7	Phase3 being prepared	HP-3150	JPN	Patch	Low back pain	Phase3 start in FY19
8	Phase3 being prepared	HP-3000	JPN	Patch	Idiopathic restless legs syndrome	Under consideration
9	Phase 2	HP-5000	USA	Patch	Osteoarthritis of the knee	Phase3 start in FY20
10	Phase2	HP-5070	JPN	Transdermal	Primary local hyperhidrosis	Phase3 start in FY20

**%Yellow-highlighted parts are changes from the previous announcement made on Oct. 10<sup>th</sup>, 2018** 

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# **Additional data**

## $Noven \ PL$ - Performance comparison with the previous period -

### Unit:\$ thousand

	Actual performance for FY02/18 (Q3)	Actual performance for FY02/19 (Q3)	Change	Percentage Change
Net sales *	135,886	124,706	-11,179	-8.2%
CoGS	70,956	61,871	-9,084	-12.8%
as a % of sales	52.2%	49.6%		
SG&A costs	44,215	46,138	+1,923	+4.3%
Sales promotion costs	2,001	2,536	+534	+26.7%
Advertising costs	522	1,784	+1,261	+241.4%
R&D spending	19,353	17,790	-1,562	-8.1%
Others	22,337	24,027	+1,689	+7.6%
Operating profits	20,714	16,695	-4,018	-19.4%
Nonoperating balance	6,913	1,822	-5,090	-73.6%
Pretax profits	27,627	18,518	-9,109	-33.0%
Net profits	20,720	14,999	-5,720	-27.6%

\* Results before consolidated adjustment.

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