Hisamitsu Pharmaceutical Co., Inc. FY02/2019 Results

and Outlook for the FY02/2020

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.

> Hisamitsu Pharmaceutical Co., Inc. Apr. 10th, 2019

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Agenda

FY02/2019 Results

- **1.** Looking back on the FY02/2019
- **2.** Consolidated PL
- **3.** Sales results by region
- 4. Sales results by product
- 5. Trends of Second-generation non-steroidal anti-inflammatory patch in Japan
- 6. R&D Pipeline

Outlook for the FY02/2020

- 7. Forecast of Consolidated PL
- 8. Forecast of Sales by region
- **9.** Forecast of Sales by product
- **10.** Forecast of dividends

Additional data



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

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(•Launch of Allesaga® Tape 4mg, 8mg (Transdermal, Allergic rhinitis treatment patch)
	Noven announces successful resolution of FDA warning letter
	•HFT-290 (a transdermal, pain management patch FENTOS® TAPE)
	Approval of supplemental new drug application (NDA) for the addition of a new 0.5 mg dose
Rx	•HP-3000 (a transdermal drug for treating Parkinson's disease)
Business	Application for manufacturing and marketing approval
	•HP-5070 (a transdermal drug for the treatment of primary local hyperhidrosis)
	Commencement of Phase II Clinical Study in Japan
	• Approval for manufacturing and marketing approval of OABLOK®PATCH in Taiwan
	(Transdermal, Overactive bladder treatment patch)
	•HFT-290 (a transdermal, pain management patch FENTOS® TAPE)
	Listing on the NHI drug price standard and marketing of a new dose 0.5 mg
	•The Sales transfer of the transdermal pain management patch NORSPAN® TAPE
	•HFT-290 (a transdermal, pain management patch FENTOS® TAPE)
	Completion of Phase III clinical study in opioid analgesic naïve patients
	·HP-3070(a transdermal Patch for the Treatment of Schizophrenia)
	A new drug application for in the U.S.
	·HP-3000 (a transdermal drug for treating Parkinson's disease)
	Conclusion of commercialization Agreement in Japan

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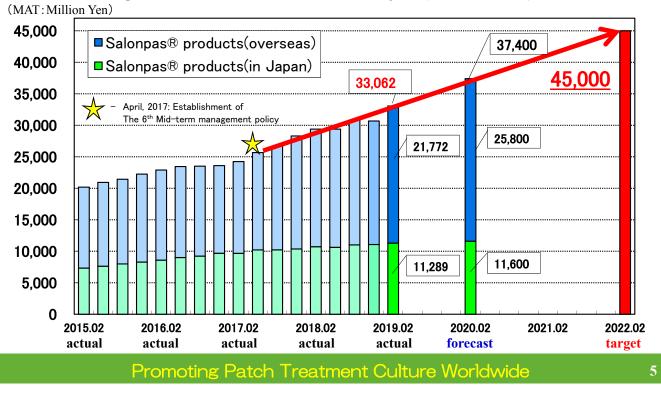
1. Looking back on the FY02/2019 (2)

	•Launch of Butenalock® Vα cream 18g, liquid 18mL							
ОТС	Launch of Salonpas® 120 patches							
Business	•Launch of Nobinobi [®] Salonsip [®] Fα							
	•Launch of Nobinobi® Salonsip® F new package, 20 patches, 40 patches							
	•Launch of Feitas® Zα DICSAS® (Hot)							
	Launch of Allegra® FX 56 tablets							
Others	 "Hisamitsu Springs" 2017-18 season V • Premier League (for women) ranked at 1st (for the 6th time in 2 years.) •Salonpas Named the World's No. 1 OTC Topical AnalgesicPatch Brand*1for the second Consecutive Year 							
	•Launch of Butenalock [®] antiseptic and antibacterial hand spray							
	• "Hisamitsu Springs" became champion at the 73nd National Sports Festival held in Fukui prefecture (2 consecutive years 8 round)							
	• The acquisition company's own shares (1,000,000 stocks)							
	• "Hisamitsu Springs" The Empress cup all-Japan volleyball championship ranked at 1st (2 consecutive years 8 round)							
	•Completion of the acquisition company's own shares (1,000,000 stocks)							
	• Subsidiary's Share Transfer							

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



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



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2. Consolidated PL (1) - Comparison with the previous period performance - Material

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					Unit:¥ million
	Actual performance for FY02/18	Actual performance for FY02/19	Change	Percentage Change	Earnings forecast for FY02/19 (Q1-Q4) *
Net sales	148,466	143,408	-5,057	-3.4%	148,500
CoGS	55,688	54,727	-960	-1.7%	56,000
as a % of sales	37.5%	38.2%			37.7%
SG&A costs	65,836	66,401	+564	+0.9%	68,500
Sales promotion costs	13,227	13,283	+56	+0.4%	15,000
Advertising costs	10,987	13,089	+2,102	+19.1%	13,700
R&D spending	15,076	13,032	-2,043	-13.6%	14,600
Others	26,545	26,995	+450	+1.7%	25,200
Operating profits	26,940	22,278	-4,661	-17.3%	24,000
Recurring profits	28,245	24,647	-3,598	-12.7%	26,300
Net profits	19,119	19,204	+85	+0.4%	19,200
Exchange rate (¥/USD)	¥112.04	¥110.39			¥110.00

<Changes in Presentation>

From the year ended February 28, 2019, "Royalty income" and others have been recorded under "Net sales." (Figures for the year ended February 28, 2018 have been reclassified under the same standards.)

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

Unit:¥ million

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	Actual performance for FY02/18 (Q1–Q4)	Actual performance for FY02/19 (Q1-Q4)	Change	Main factor
Net sales	148,466	143,408	-5,057	
CoGS	55,688	54,727	-960	Affected by the drug price revision. Change of sales mix.
as a % of sales	37.5%	38.2%		
SG&A costs	65,836	66,401	+564	
Sales promotion costs	13,227	13,283	+56	
Advertising costs	10,987	13,089	+2,102	•Active investment at Japan and Overseas.
R&D spending	15,076	13,032	-2,043	[FY02/18] •Completion of PⅢ for HP-3000, HP-3070.
Others	26,545	26,995	+450	
Operating profits	26,940	22,278	-4,661	
Nonoperating balance	1,305	2,368	+1,063	 Increase in Equity-method investment profits. Decrease in foreign exchange losses.
Recurring profits	28,245	24,467	-3,598	
Extraordinary balance	-551	1,026	+1,557	[FY02/19] •gain on sales of investment securities. [FY02/18] •impairment loss.
Net profits	19,119	19,204	+85	
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3. Sales results by region

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		Actual performance for FY02/18 (Q1-Q4)	Actual performance for FY02/19 (Q1-Q4)	change	percentage Change
Net sales		148,466	143,408	-5,057	-3.4%
Rx Business	Japan	73,544	67,384	-6,160	-8.4%
Rx Business	USA	18,184	15,628	-2,556	-14.1%
	Other regions	3,327	2,869	-458	-13.8%
OTC Business	Japan	26,865	28,529	+1,663	+6.2%
	USA	9,698	11,137	+1,438	+14.8%
	Other regions	13,455	14,413	+957	+7.1%
Others	Japan	3,389	3,447	+58	+1.7%

Unit:¥ million

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

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								1	Unit:¥ n	nillion
		al performa or FY02/1			Change			Percentage Change		
	Total	Japan	Overseas	-	Total	Japan	Overseas	Total	Japan	Overseas
Rx Business	85,881	67,384	18,497	-	9,175	-6,160	-3,015	-9.7%	-8.4%	-14.0%
Fentos _® Tape	4,852	4,852	_		-65	-65	_	-1.3%	-1.3%	_
Norspan _® Tape	2,060	2,060	-		-18	-18		-0.9%	-0.9%	-
Neoxy _® Tape	696	696	-		-138	-138	-	-16.6%	-16.6%	-
Abstral [®]	209	209	_		-8	-8	-	-3.7%	-3.7%	_
Allesaga _® Tape	230	230	-		+230	+230	-	-	-	-
Mohrus _® Tape	42,115	41,929	186		-7,620	-7,623	+3	-15.3%	-15.4%	+1.7%
Mohrus _® Pap	7,447	7,447	-		-951	-951	-	-11.3%	-11.3%	-
(Mohrus _® Pap XR)	5,366	5,366	_		-225	-225	-	-4.0%	-4.0%	_
Others	10,987	9,957	1,029		+2,501	+2,414	+87	+29.5%	+32.0%	+9.3%
Minivelle [®] products	6,098	-	6,098		-1,529	-	-1,529	-20.1%	-	-20.1%
Vivelle-Dot [®] products	4,190	-	4,190		-649	-	-649	-13.4%	-	-13.4%
CombiPatch [®] products	4,428	-	4,428		+251	-	+251	+6.0%	-	+6.0%
Brisdelle®	0	-	0		+116	-	+116	-	-	-
Daytrana [®]	2,520	-	2,520		-650	_	-650	-20.5%	-	-20.5%
Others of Noven products	43	-	43		-644	_	-644	-93.7%	-	-93.7%

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4. Sales results by product (2) - OTC Business -

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								UIIII.+		
		Actual performance for FY02/19			Change			Percentage Change		
	Total	Japan	Overseas	Total	Japan	Overseas	Total	Japan	Overseas	
OTC Business	54,079	28,529	25,550	+4,059	+1,663	+2,396	+8.1%	+6.2%	+10.3%	
Salonpas _® products	33,062	11,289	21,772	+3,670	+569	+3,100	+12.5%	+5.3%	+16.6%	
Salonsip _® products	3,414	2,240	1,173	-1,260	-1,000	-260	-27.0%	-30.9%	-18.2%	
Air _® Salonpas _® products	1,789	1,057	732	+72	+63	+9	+4.2%	+6.4%	+1.3%	
Feitas _® products	5,811	5,811	-	+632	+632	-	+12.2%	+12.2%	-	
Butenalock _® products	1,672	1,672	-	+104	+104	-	+6.7%	+6.7%	-	
Allegra [®] FX	4,509	4,509	-	+1,144	+1,144	_	+34.0%	+34.0%	-	
Others	3,820	1,948	1,872	-305	+148	-453	-7.4%	+8.3%	-19.5%	

Unit:¥ million

5. 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 Feb.2019(MAT) YoY Hydrogel Tape Patch 1,000 Volume Basis 5,172 (million) 96.2% 83.1% 16.9% Monetary Basis ¥135.221 (million) 90.5% 85.0% 15.0% 0 04,08 05,02 05,08 06,02 06,08 07,02 07,08 08,02 08,02 08,02 08,02 09,08 10,02 10,08 3,0 Copyright ©2019 IQVIA./Calculated based on JPM data(~Feb.2019)/Reprinted with permission Promoting Patch Treatment Culture Worldwide

5.Trends of second-generation non-steroidal anti-inflammatory patch in Japan (2)

Change in shares of the Mohrus_® products on monetary-basis 55.0% Mohrus® Tape + Mohrus® Pap 50.0% Feb. 2018 :43.1% → Feb. 2019 :40.6% (Nov. 2018:41.5%) 45.0% 40.0% 35.0% **Mohrus®** Tape 30.0% Feb. 2018 : $36.4\% \rightarrow$ Feb. 2019 : 34.1%25.0% **Mohrus®** Pap 20.0% Feb. 2018 : 6.7% → Feb. 2019 : 6.6% 15.0% 10.0% 5.0% 0.0% $\begin{array}{c} 06,02\\ 06,02\\ 06,01\\ 07,05\\ 07,05\\ 07,05\\ 07,05\\ 07,05\\ 07,05\\ 07,05\\ 07,05\\ 07,05\\ 07,02\\ 00,07\\ 00,01\\ 00$ Copyright ©2019 IQVIA./Calculated based on JPM data(~Feb.2019)/Reprinted with permission

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6. 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 ĭ 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*	ATS	USA	Patch	Attention Deficit Hyperactivity Disorder (ADHD)	To be filed in FY20
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	Phase 2	HP-5070	JPN	Transdermal	Primary local hyperhidrosis	Phase3 start in FY20

*Conduct of 4 studies including not large efficacy and safety trial, but usability test.

%Yellow-highlighted parts are changes from the previous announcement made on Jan. 11th, 2019

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Outlook for the FY02/2020

7. Forecast of Consolidated PL

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			U	nit:¥ million
	ActualFull-year earingperformance forforecast forFY02/19FY02/20(Q1-Q4)(Q1-Q4)		Change	Percentage Change
Net sales	143,408	143,500	+92	+0.1%
CoGS	54,727	52,600	-2,127	-3.9%
as a % of sales	38.2%	36.7%		
SG&A costs	66,401	68,000	+1,599	+2.4%
Sales promotion costs	13,283	13,500	+217	+1.6%
Advertising costs	13,089	14,800	+1,711	+13.1%
R&D spending	13,032	13,000	-32	-0.2%
Others	26,995	26,700	-295	-1.1%
Operating profits	22,278	22,900	+622	+2.8%
Recurring profits	24,647	25,500	+853	+3.5%
Net profits	19,204	19,400	+196	+1.0%
Exchange rate(¥/USD)	110.39円	110.00円		

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8. Forecast of Sales results by region

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Unit:¥ million

		Actual performance for FY02/19 (Q1-Q4)	Full-year earnings forecast for FY02/20 (Q1-Q4)	Change	Percentage Change
Net sales		143,408	143,500	+92	+0.1%
Rx Business	Japan	67,384	66,100	-1,284	-1.9%
	USA	15,628	10,600	-5,028	-32.2%
	Other regions	2,869	3,700	+831	+29.0%
OTC Business	Japan	28,529	29,600	+1,071	+3.8%
	USA	11,137	12,900	+1,763	+15.8%
	Other regions	14,413	17,800	+3,387	+23.5%
Others	Japan	3,447	2,800	-647	-18.8%

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9. Forecast of Sales by product (1) - Rx Business -

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Unit:¥ million

	Earnings forecast for FY02/20 (Q1-Q4)				Change			Percentage Change		
	Total	Japan	Overseas	Total	Japan	Overseas	Total	Japan	Overseas	
Rx Business	80,400	66,100	14,300	-5,481	-1,284	-4,197	-6.4%	-1.9%	-22.7%	
Fentos _® Tape	4,100	4,100	-	-752	-752	-	-15.5%	-15.5%	_	
Neoxy _® Tape	800	800	-	+104	+104	-	+14.9%	+14.9%	_	
Abstral [®]	200	200	-	-9	-9	-	-4.3%	-4.3%	-	
Allesaga _® Tape	2,400	2,400		+2,170	+2,170		+943.5%	+943.5%		
Mohrus _® Tape	38,100	37,800	300	-4,015	-4,129	+114	-9.5%	-9.8%	+61.3%	
Mohrus _® Pap	7,300	7,300	-	-147	-147	-	-2.0%	-2.0%	-	
(Mohrus _® Pap XR)	5,400	5,400	-	+34	+34	-	+0.6%	+0.6%	-	
Others	14,800	13,500	1,300	+1,754	+1,483	+271	+13.4%	+12.3%	+26.3%	
Minivelle [®] products	2,500	-	2,500	-3,598	-	-3,598	-59.0%	-	-59.0%	
Vivelle-Dot [®] products	3,400	-	3,400	-790	-	-790	-18.9%	-	-18.9%	
CombiPatch [®] products	4,300	-	4,300	-128	-	-128	-2.9%	-	-2.9%	
Daytrana®	2,500	_	2,500	-20	_	-20	-0.8%	-	-0.8%	
Others of Noven products	_	-	-	-43	_	-43	-	-	-	

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9. Forecast of Sales by product (2) - OTC Business -

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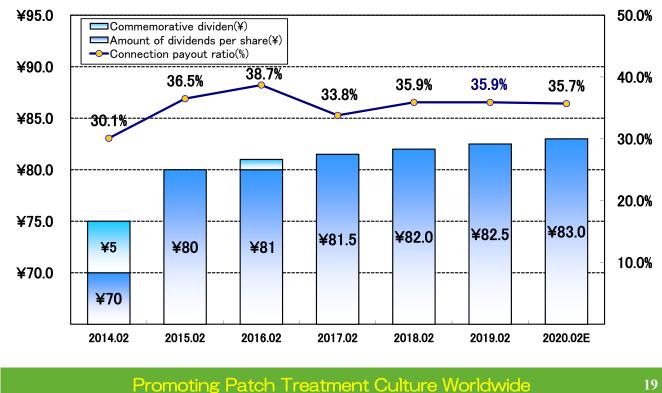
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	Earnings forecast for FY02/20 (Q1-Q4)			Change			Percentage Change		
	Total	Japan	Overseas	Total	Japan	Overseas	Total	Japan	Overseas
OTC Business	60,300	29,600	30,700	+6,221	+1,071	+5,150	+11.5%	+3.8%	+20.2%
Salonpas _® products	37,400	11,600	25,800	+4,337	+310	+4,027	+13.1%	+2.8%	+18.5%
Salonsip _® products	4,100	2,900	1,200	+685	+659	+26	+20.1%	+29.5%	+2.3%
$Air_{{}_{\mathbb{R}}}$ Salonpas $_{{}_{\mathbb{R}}}$ products	2,100	1,200	900	+311	+143	+168	+17.4%	+13.5%	+23.0%
Feitas _® products	5,900	5,900	_	+88	+88	-	+1.5%	+1.5%	-
Butenalock _® products	1,900	1,900	_	+227	+227		+13.6%	+13.6%	-
Allegra [®] FX	3,800	3,800	_	-708	-708	-	-15.7%	-15.7%	_
Others	5,100	2,300	2,800	+1,280	+352	+928	+33.5%	+18.1%	+49.6%

Unit:¥ million

10. Forecast of dividends

For the term ending February 2019, the consolidated dividend payout ratio is predicted to be 35.9% and the payout is expected to be ¥82.5. (* Midterm dividend ¥41.25 predicted.)





Additional data

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Change to Sales results by region

[Conventional net sales classification]

L						
	Actual performance for FY02/18	performance performance		Main factor		
Net sales	148,466	143,408	-5,057			
Hisamitsu (Non consolidated)	112,505	109,269	-3,236	 Decrease in sales of Rx Business. Increase in sales of OTC Business. Increase in sales of Intl Business. 		
Noven	20,817	17,808	-3,008	•Decrease in sales of major products.		
Others *	15,143	16,330	+1,187	 Increase in sales of overseas subsidiaries. 		

* "Others" includes consolidated adjustment.

Consolidated sales]_	Non Consolidated sales of Hisamitsu	-	Sales of Noven	=	Sales of Others
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(issues)

•Sales of overseas is not clear, because "Others" includes consolidated adjustment.

•Sales of USA that is the records of sales performance next to Japan, is not clear.

Change from conventional net sales classification to only consolidated sales classification, Adding the sales results by region.

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