Hisamitsu Pharmaceutical Co., Inc. Q2 FY02/2020 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. Oct. 10th, 2019

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Agenda

- 1. Looking back on the Q2 FY02/2020
- 2. Summary of Financial Results for Q2 FY02/2020
- 3. Consolidated PL
- 4. Sales results by region
- 5. Sales results by product
- 6. Trends of Second-generation non-steroidal anti-inflammatory patch in Japan
- 7. R&D Pipeline

1. Looking back on the Q2 FY02/2020 (1)

 May ·HP-3150 (an analgesic transdermal drug containing NSAIDs) Completion of the Phase III clinical study in Japan for "carcinomatous pain". ·HP-5070 (a transdermal drug for the treatment of primary local hyperhidrosis Completion of Phase II clinical study in Japan. Jun. •Transfer of marketing and manufacturing approval and distribution rights for the transdermal follicle and luteinizing hormone product "Menoaid® Combipatch".
Aug. • Application for manufacturing and marketing approval of the additional indications of opioid analgesic naïve cancer pain relief of FENTOS® TAPE (Transdermal, pain management patch, Development code: HFT-290) in Japan

- **Sep. 1, 2019 : Launch of the transdermal follicle and luteinizing hormone product "Menoaid® Combipatch"

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1. Looking back on the Q2 FY02/2020 (2)

HARUROPI_® TAPE (development code: HP-3000)

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Trade name	HARUROPI® TAPE 8 mg HARUROPI® TAPE 16 mg HARUROPI® TAPE 24 mg HARUROPI® TAPE 32 mg HARUROPI® TAPE 40 mg
Active pharmaceutical ingredient	Ropinirole hydrochloride
Indication	Parkinson's disease
Dosage and Administration	Usually, for adults initially apply 8mg formulation as Ropinirole hydrochloride once daily, observing the progress, increased as needed the daily dose by 8 mg at intervals of 1 week or more. For any dose, apply once daily to the skin of the chest, abdomen, flank, thigh or upper arm and replace every 24 hours. Further, the dosage can be adjusted according to the age and the symptoms, the daily dosage should not exceed 64mg as Ropinirole hydrochloride.
Size of formulation	5.33 cm ² (HARUROPI _® TAPE 8 mg) 10.67 cm ² (HARUROPI _® TAPE 16 mg) 16.00 cm ² (HARUROPI _® TAPE 24 mg) 21.33 cm ² (HARUROPI _® TAPE 32 mg) 26.67 cm ² (HARUROPI _® TAPE 40 mg)

1. Looking back on the Q2 FY02/2020 (3)

Mar. •Launch of Feitas_® Shippu, Feitas_® Shippu(Hot) new package.

Apr. •Launch of Kodomo Robinai plus new package.

Jun. •Launch of Air_® Salonpas_® Jet α 25ml new package.

Jul. •Launch of Nobinobi_® Salonsip_® F new package, 10 patches.

Aug •Launch of Feitas_® Zα DICSAS_® Gel.







Mar. • Launch of Air_® Salonpas_® Ice-ing Spray 490mL.

Apr. • "Hisamitsu Springs" 2018-19 V. LEAGUE DIVISION 1 (for women) ranked at 1st .(2nd consecutive years 7 round)

May • Salonpas_® Named the World's No. 1 OTC Topical AnalgesicPatch Brand 1 for the 3rd consecutive years.

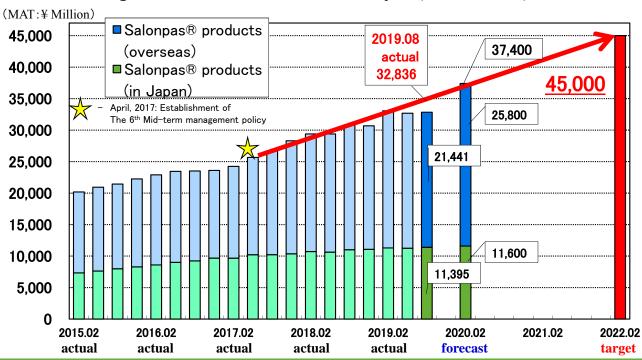
Jul. • Purchase and retirement of treasury shares.

*Sep. 30, 2019: Completion of purchase of treasury shares.

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1. Looking back on the Q2 FY02/2020 (4)



2. Summary of Financial Results for Q2 FY02/2020

Consolidated

Unit:¥ million

	Q2 FY02/2020 FY02/2020		′2020
	Actual	Forecast	Progress rate
Net sales	63,401	143,500	44.2%
Operating profits	10,190	22,900	44.5%
Recurring profits	10,641	25,500	41.7%
Net profits	7,548	19,400	38.9%

XNo change is made on forecast.

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

Unit:¥ million

	Actual performance for FY02/19 (Q2)	Actual performance for FY02/20 (Q2)	Change	Percentage Change
Net sales	69,400	63,401	-5,999	-8.6%
CoGS	26,130	22,892	-3,238	-12.4%
as a % of sales	37.7%	36.1%		
SG&A costs	32,024	30,319	-1,705	-5.3%
Sales promotion costs	6,439	6,131	-307	-4.8%
Advertising costs	6,229	6,551	+322	+5.2%
R&D spending	6,329	5,330	-998	-15.8%
Others	13,027	12,305	-721	-5.5%
Operating profits	11,245	10,190	-1,055	-9.4%
Recurring profits	12,012	10,641	-1,371	-11.4%
Net profits	9,158	7,548	-1,609	-17.6%

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

Unit:¥ million

	Quarterly actual performance for FY02/19 (Q2)	Quarterly actual performance for FY02/20 (Q2)	Change	Percentage Change
Net sales	29,233	34,168	+4,935	+16.9%
CoGS	10,901	11,990	+1,089	+10.0%
as a % of sales	37.3%	35.1%		
SG&A costs	15,552	14,766	-786	-5.1%
Sales promotion costs	2,987	3,144	+156	+5.2%
Advertising costs	3,309	3,241	-68	-2.1%
R&D spending	2,978	2,351	-627	-21.1%
Others	6,276	6,028	-247	-3.9%
Operating profits	2,778	7,411	+4,632	+166.7%
Recurring profits	2,863	7,777	+4,913	+171.6%
Net profits	1,913	5,634	+3,720	+194.4%

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

Unit:¥ million

				Omt.+ million
	Actual performance for FY02/19 (Q2)	Actual performance for FY02/20 (Q2)	Change	Main factor
Net sales	69,400	63,401	-5,999	
CoGS	26,130	22,892	-3,238	•Change of sales mix.
as a % of sales	37.7%	36.1%		
SG&A costs	32,024	30,319	-1,705	
Sales promotion costs	6,439	6,131	-307	Japan: Influence of decrease in sales.Overseas: Engaging in active sales promotion.
Advertising costs	6,229	6,551	+322	-Aggressive advertising in Overseas.
R&D spending	6,329	5,330	-998	▪Completion of Phase Ⅲ clinical study.
Others	13,027	12,305	-721	•Decrease in amortization cost of goodwill.
Operating profits	11,245	10,190	-1,055	
Nonoperating balance	767	451	-315	•Increase in foreign exchange losses.
Recurring profits	12,012	10,641	-1,371	
Extraordinary balance	208	-4	-212	
Net profits	9,158	7,548	-1,609	

4. Sales results by region

Unit:¥ million

		Actual performance for FY02/19 (Q2)	Actual performance for FY02/20 (Q2)	change	percentage Change
Net sales		69,400	63,401	-5,999	-8.6%
	Japan	32,578	29,467	-3,110	-9.5%
Rx Business	USA	8,066	6,577	-1,488	-18.5%
	Other regions	1,440	1,683	+243	+16.9%
	Japan	14,619	13,659	-959	-6.6%
OTC Business	USA	5,836	5,972	+135	+2.3%
	Other regions	5,138	4,727	-411	-8.0%
Others	Japan	1,720	1,313	-407	-23.7%

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

Unit:¥ million

	Actual performance for FY02/20 Q2				
	Total Japan Overse				
Rx Business	37,728	29,467	8,261		
Fentos _® Tape	2,176	2,176	_		
Neoxy _® Tape	313	313	_		
Abstral [®]	102	102	-		
Allesaga _® Tape	98	98	-		
Mohrus _® Tape	19,454	19,424	30		
Mohrus _® Pap	3,315	3,315	-		
(Mohrus _® Pap XR)	2,403	2,403	-		
Others	4,400	3,888	512		
Minivelle® products	1,656	-	1,656		
Vivelle-Dot® products	3,051	-	3,051		
CombiPatch® products	1,924	148	1,776		
Daytrana [®]	1,156	_	1,156		
Others of Noven products	78	_	78		

Takal	Change	Overse		entage Cha	
Total -4,356	Japan -3,110	Overseas -1,245	Total -10.4%	Japan −9.5%	Overseas
		1,240			10.17
-475	-475	_	-17.9%	-17.9%	
-32	-32	_	-9.3%	-9.3%	_
-2	-2	-	-2.1%	-2.1%	_
-4	-4	_	-4.2%	-4.2%	-
-1,351	-1,343	-7	-6.5%	-6.5%	-20.5%
-412	-412	_	-11.1%	-11.1%	-
-258	-258	_	-9.7%	-9.7%	-
-880	-989	+109	-16.7%	-20.3%	+27.1%
-1,785	_	-1,785	-51.9%	-	-51.9%
+707	_	+707	+30.2%	_	+30.2%
-247	+148	-396	-11.4%	_	-18.2%
+47	_	+47	+4.3%	_	+4.3%
+78	_	+78	-	_	_

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

Unit:¥ million

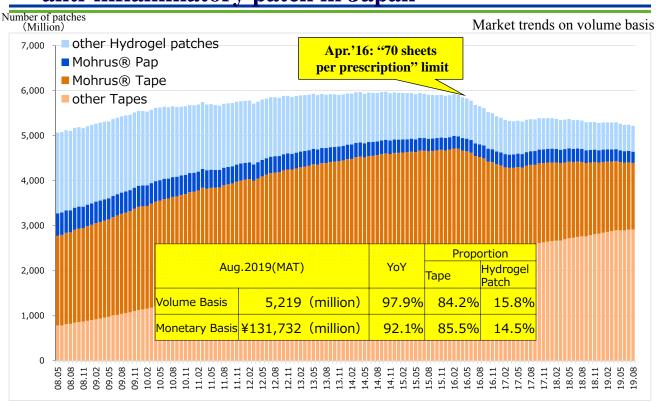
	Actual performance for FY02/20 Q2			
	Total	Japan	Overseas	
OTC Business	24,359	13,659	10,699	
Salonpas _® products	15,382	5,972	9,409	
Salonsip _® products	1,636	1,207	428	
Air _® Salonpas _® products	907	671	235	
Feitas _® products	3,169	3,169	_	
Butenalock _® products	1,124	1,124	-	
Allegra [®] FX	644	644	_	
Others	1,495	868	626	

	Change		Perc	entage Cha	ange
Total	Japan	Overseas	Total	Japan	Overseas
-1,235	-959	-275	-4.8%	-6.6%	-2.5%
-224	+106	-331	-1.4%	+1.8%	-3.4%
-178	-141	-36	-9.8%	-10.5%	-7.8%
-110	-48	-62	-10.9%	-6.7%	-20.9%
+243	+243	_	+8.3%	+8.3%	_
-103	-103	_	-8.4%	-8.4%	_
-776	-776	_	-54.7%	-54.7%	_
-84	-239	+154	-5.4%	-21.6%	+32.8%

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



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7. R&D Pipeline

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

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

XYellow-highlighted parts are changes from the previous announcement made on Jul. 10th, 2019

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