

# Hisamitsu Pharmaceutical Co., Inc.

## Q3 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.

Jan. 10<sup>th</sup>, 2020

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### Agenda

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- 1. Looking back on the Q3 FY02/2020**
- 2. Summary of Financial Results for Q3 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**

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# 1. Looking back on the Q3 FY02/2020 (1)

Rx Business	May	<ul style="list-style-type: none"> <li>·HP-3150 (an analgesic transdermal drug containing NSAIDs) Completion of the Phase III clinical study in Japan for “carcinomatous pain”.</li> <li>·HP-5070 (a transdermal drug for the treatment of primary local hyperhidrosis) Completion of Phase II clinical study in Japan.</li> </ul>
	Jun.	<ul style="list-style-type: none"> <li>·Transfer of marketing and manufacturing approval and distribution rights for the transdermal follicle and luteinizing hormone product “Menoaid® Combipatch”.</li> </ul>
	Aug.	<ul style="list-style-type: none"> <li>·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.</li> </ul>
	Sep.	<ul style="list-style-type: none"> <li>·Launch of the transdermal follicle and luteinizing hormone product “Menoaid® Combipatch”</li> <li>·Approval for manufacturing and marketing approval of HARUROPI® TAPE in Japan (Transdermal, Parkinson’s disease treatment patch, development code: HP-3000)</li> </ul>
	Oct.	<ul style="list-style-type: none"> <li>·FDA approval for SECUADO® in the U.S.(Transdermal, schizophrenia treatment patch, development code: HP-3070)</li> </ul>
	Nov.	<ul style="list-style-type: none"> <li>·HP-5000 (Transdermal, pain relief and anti-inflammatory patch) Completion of Phase II clinical study in the U.S.</li> </ul>

※Dec. 17, 2019 : Launch of HARUROPI® TAPE (Transdermal, Parkinson’s disease treatment patch.)

※Jan. 9, 2020 : HP-3150 (an analgesic transdermal drug containing NSAIDs) Commencement of Phase III Clinical Study for low back pain, humeroscapular peri-arthritis, cervico-omo-brachial syndrome and tenosynovitis in Japan

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# 1. Looking back on the Q3 FY02/2020 (2)

OTC Business	Mar	<ul style="list-style-type: none"> <li>·Launch of Feitas® Shippu, Feitas® Shippu(Hot) new package.</li> </ul>
	Apr.	<ul style="list-style-type: none"> <li>·Launch of Kodomo Robinai plus new package.</li> </ul>
	Jun.	<ul style="list-style-type: none"> <li>·Launch of Air® Salonpas® Jet α 25ml new package.</li> </ul>
	Jul.	<ul style="list-style-type: none"> <li>·Launch of Nobinobi® Salonsip® F new package, 10 patches.</li> </ul>
	Aug.	<ul style="list-style-type: none"> <li>·Launch of Feitas® Zα DICSAS® Gel.</li> </ul>

Others	Mar.	<ul style="list-style-type: none"> <li>· Launch of Air® Salonpas® Ice-ing Spray 490mL.</li> </ul>
	Apr.	<ul style="list-style-type: none"> <li>·“Hisamitsu Springs” 2018-19 V. LEAGUE DIVISION 1 (for women) ranked at 1<sup>st</sup>.(2nd consecutive years 7 round)</li> </ul>
	May	<ul style="list-style-type: none"> <li>·Salonpas® Named the World’s No. 1 OTC Topical Analgesic Patch Brand 1 for the 3rd consecutive years.</li> </ul>
	Jul.	<ul style="list-style-type: none"> <li>·Purchase and retirement of treasury shares.</li> </ul>
	Sep.	<ul style="list-style-type: none"> <li>·Completion of purchase of treasury shares.</li> </ul>
	Nov.	<ul style="list-style-type: none"> <li>·Completion of cancellation of treasury shares.</li> </ul>

※Jan. 10, 2020 : Establishment of new company in Malaysia

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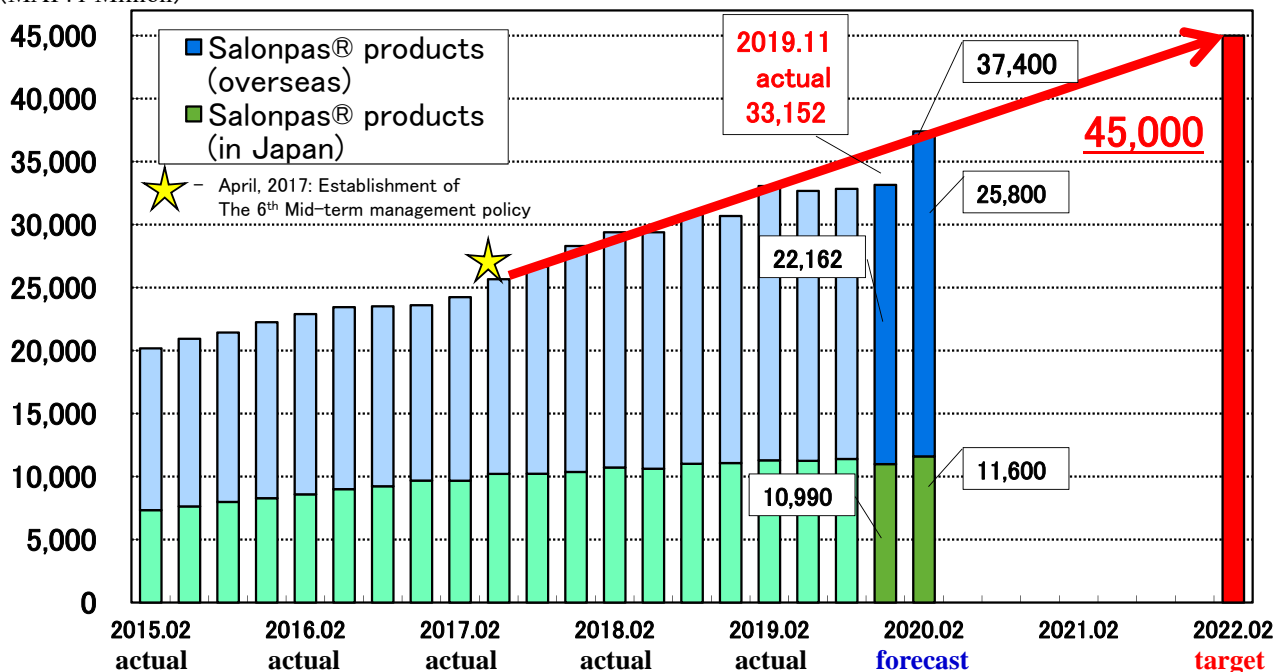
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# 1. Looking back on the Q3 FY02/2020 (3)

<Sales transition of Salonpas® products>

Target: annual sales of 45 billion yen(at FY02/22)

(MAT : ¥ Million)



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# 2. Summary of Financial Results for Q3 FY02/2020

## Consolidated

Unit: ¥ million

	Q3 FY02/2020	FY02/2020	
	Actual	Forecast	Progress rate
Net sales	99,078	143,500	69.0%
Operating profits	18,417	22,900	80.4%
Recurring profits	19,917	25,500	78.1%
Net profits	15,420	19,400	79.5%

※No 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 (Q3)	Actual performance for FY02/20 (Q3)	Change	Percentage Change
<b>Net sales</b>	<b>102,587</b>	<b>99,078</b>	<b>-3,509</b>	<b>-3.4%</b>
CoGS	38,175	34,554	-3,620	-9.5%
as a % of sales	37.2%	34.9%		
SG&A costs	48,458	46,106	-2,351	-4.9%
Sales promotion costs	10,155	9,655	-499	-4.9%
Advertising costs	9,399	10,154	+754	+8.0%
R&D spending	9,369	7,547	-1,822	-19.4%
Others	19,533	18,749	-784	-4.0%
<b>Operating profits</b>	<b>15,954</b>	<b>18,417</b>	<b>+2,463</b>	<b>+15.4%</b>
<b>Recurring profits</b>	<b>17,412</b>	<b>19,917</b>	<b>+2,505</b>	<b>+14.4%</b>
<b>Net profits</b>	<b>13,329</b>	<b>15,420</b>	<b>+2,091</b>	<b>+15.7%</b>

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

Unit:¥ million

	Actual performance for FY02/19 (Q3)	Actual performance for FY02/20 (Q3)	Change	Main factor
<b>Net sales</b>	<b>102,587</b>	<b>99,078</b>	<b>-3,509</b>	
CoGS	38,175	34,554	-3,620	
as a % of sales	37.2%	34.9%		<ul style="list-style-type: none"> <li>• Production efficiency, and cost reduction.</li> <li>• Sales recognition of the milestone payment on approval.</li> </ul>
SG&A costs	48,458	46,106	-2,351	
Sales promotion costs	10,155	9,655	-499	<ul style="list-style-type: none"> <li>• Japan: Influence of decrease in sales.</li> <li>• Overseas: Engaging in active sales promotion.</li> </ul>
Advertising costs	9,399	10,154	+754	• Aggressive advertising in Japan and Overseas.
R&D spending	9,369	7,547	-1,822	• Completion of Phase III clinical study.
Others	19,533	18,749	-784	• Decrease in amortization cost of goodwill.
<b>Operating profits</b>	<b>15,954</b>	<b>18,417</b>	<b>+2,463</b>	
Nonoperating balance	1,457	1,500	+42	
<b>Recurring profits</b>	<b>17,412</b>	<b>19,917</b>	<b>+2,505</b>	
Extraordinary balance	209	+1,600	+1,391	• Appropriation of the settlement received.
<b>Net profits</b>	<b>13,329</b>	<b>15,420</b>	<b>+2,091</b>	

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## 4. Sales results by region

Unit:¥ million

		Actual performance for FY02/19 (Q3)	Actual performance for FY02/20 (Q3)	change	percentage Change
<b>Net sales</b>		<b>102,587</b>	<b>99,078</b>	<b>-3,509</b>	<b>-3.4%</b>
Rx Business	Japan	49,358	49,468	+109	+0.2%
	USA	11,867	9,233	-2,633	-22.2%
	Other regions	2,072	2,642	+569	+27.5%
OTC Business	Japan	20,579	19,223	-1,355	-6.6%
	USA	8,231	8,644	+413	+5.0%
	Other regions	7,896	7,897	+0	+0.0%
Others	Japan	2,582	1,969	-613	-23.7%

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

Unit:¥ million

	Actual performance for FY02/20 Q3			Change			Percentage Change		
	Total	Japan	Overseas	Total	Japan	Overseas	Total	Japan	Overseas
<b>Rx Business</b>	<b>61,344</b>	<b>49,468</b>	<b>11,875</b>	<b>-1,954</b>	<b>+109</b>	<b>-2,064</b>	<b>-3.1%</b>	<b>+0.2%</b>	<b>-14.8%</b>
Fentos <sup>®</sup> Tape	3,313	3,313	-	-583	-583	-	-15.0%	-15.0%	-
Neoxy <sup>®</sup> Tape	443	443	-	-70	-70	-	-13.8%	-13.8%	-
Abstral <sup>®</sup>	152	152	-	-3	-3	-	-2.6%	-2.6%	-
Allesaga <sup>®</sup> Tape	136	136	-	+26	+26	-	+24.3%	+24.3%	-
Mohrus <sup>®</sup> Tape	28,650	28,545	105	-2,935	-3,003	+67	-9.3%	-9.5%	+177.9%
Mohrus <sup>®</sup> Pap	4,849	4,849	-	-825	-825	-	-14.5%	-14.5%	-
(Mohrus <sup>®</sup> Pap XR)	3,509	3,509	-	-553	-553	-	-13.6%	-13.6%	-
Others	12,543	11,741	802	+4,453	+4,282	+171	+55.0%	+57.4%	+27.1%
Minivelle <sup>®</sup> products	2,494	-	2,494	-2,357	-	-2,357	-48.6%	-	-48.6%
Vivelle-Dot <sup>®</sup> products	3,772	-	3,772	+473	-	+473	+14.4%	-	+14.4%
CombiPatch <sup>®</sup> products	3,117	287	2,830	-171	+287	-459	-5.2%	-	-14.0%
Daytrana <sup>®</sup>	1,793	-	1,793	-37	-	-37	-2.0%	-	-2.0%
Others of Noven products	78	-	78	+77	-	+77	-	-	-

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

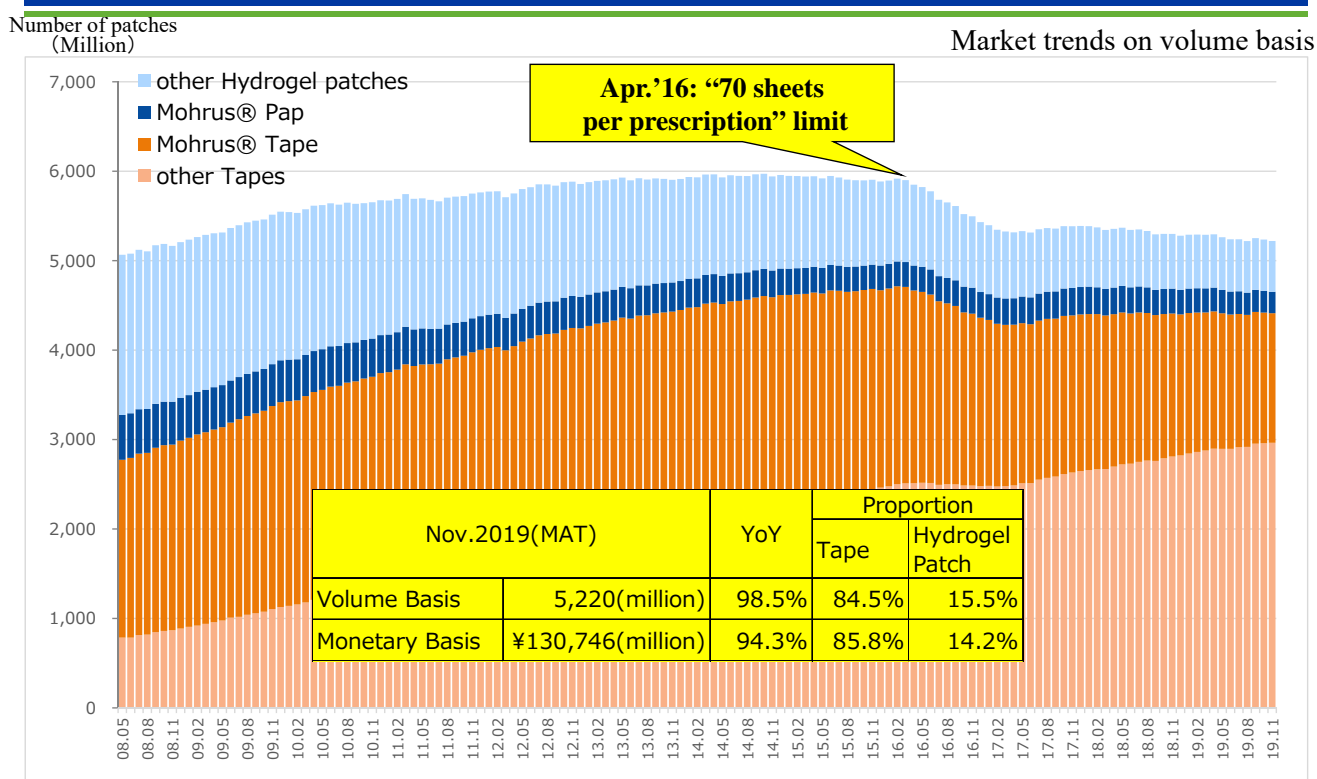
Unit:¥ million

	Actual performance for FY02/20 Q3			Change			Percentage Change		
	Total	Japan	Overseas	Total	Japan	Overseas	Total	Japan	Overseas
<b>OTC Business</b>	<b>35,765</b>	<b>19,223</b>	<b>16,541</b>	<b>-942</b>	<b>-1,355</b>	<b>+413</b>	<b>-2.6%</b>	<b>-6.6%</b>	<b>+2.6%</b>
Salonpas® products	22,828	8,439	14,388	+90	-298	+389	+0.4%	-3.4%	+2.8%
Salonsip® products	2,624	1,767	856	+55	+4	+50	+2.2%	+0.3%	+6.3%
Air® Salonpas® products	1,276	874	402	-134	-38	-96	-9.6%	-4.2%	-19.3%
Feitas® products	4,495	4,495	-	-30	-30	-	-0.7%	-0.7%	-
Butenolock® products	1,262	1,262	-	-139	-139	-	-9.9%	-9.9%	-
Allegra® FX	1,059	1,059	-	-622	-622	-	-37.0%	-37.0%	-
Others	2,218	1,324	894	-161	-231	+69	-6.8%	-14.9%	+8.5%

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



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## 7. R&D Pipeline (1)

	Stage	Theme	Target	Dosage Form	Characteristics	Next Step
1	Launched	HP-3000 (HARUROPI®TAPE)	JPN	Patch	Parkinson's disease	Launched on Dec. 17th, FY19
2	Approval	HP-3070 (SECUADO®)	USA	Patch	Schizophrenia	To be launched in FY20
3	Filed (ANDA)	HP-1010	USA	Patch	Relief of pain associated with post-herpetic neuralgia	No disclosure
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	HP-3150	JPN	Patch	Low back pain Humeroscapular peri-arthritis Cervico-omo-brachial syndrome Tenosynovitis	To be filed in FY21
8	Phase3 being prepared	HP-5070	JPN	Transdermal	Primary local hyperhidrosis	Phase3 start in FY20
9	Phase3 being prepared	HP-5000	USA	Patch	Osteoarthritis of the knee	Phase3 start in FY20
10	Phase3 being prepared	HP-3000	JPN	Patch	Idiopathic restless legs syndrome	Under consideration

\*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 Oct. 10<sup>th</sup>, 2019

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## 7. R&D Pipeline (2)

【HP-5000 : transdermal, pain relief and anti-inflammatory patch  
(generic name : Diclofenac Sodium)】

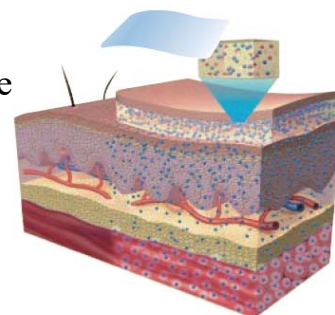
•••Phase II clinical trial in the U.S. for patients with Osteoarthritis of the knee has been completed in November, 2019. The study results suggested the investigational product was efficacious in the primary endpoint. In addition, no adverse reactions were observed that could cause major concerns in development.

Primary endpoint : Change from baseline in score at week 4

The study result : There was a statistically significant difference in the primary endpoint when compared the investigational product group with the placebo group.

<Feature of the product>

- Indication for Osteoarthritis of the knee.
- To reduce a burden that is taking the external gel preparation or external liquid preparation.
- To reduce gastrointestinal disorders caused by Oral NSAIDs.



Trans DermaSal® Technology

•••Technology to make it possible to transdermally administer water-soluble drugs that are commonly difficult to develop as transdermal formulations

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# Patch, moving into the future.



**Hisamitsu**



Tokyo 2020 Official Partner (External Pain Relief Products)



For muscle ache, muscle fatigue  
Third-class OTC drugs



For stiff shoulders, backache, muscle ache  
Third-class OTC drugs



For stiff shoulders, shoulderache, backache  
Second-class OTC drugs



For muscle ache, muscle fatigue  
Third-class OTC drugs