# Hisamitsu Pharmaceutical Co., Inc. FY02/2021 Results and Outlook for the FY02/2022

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. Apr. 8<sup>th</sup>, 2021

# **Agenda**

### **FY02/2021 Results**

- 1. Looking back on the FY02/2021
- 2. Promotion of ESG
- 3. Consolidated P&L
- 4. Sales Results by Region
- 5. Sales Results by Product
- 6. Trends of 2nd-generation non-steroidal anti-inflammatory patch in Japan
- 7. R&D Pipeline

### Outlook for the FY02/2022

- 8. Forecast of Consolidated P&L
- 9. Forecast of Sales by Region
- 10. Forecast of Sales by Product
- 11. Forecast of Dividend

# 1. Looking back on the FY02/2021 (1)

- Mar. ·Launch of transdermal, schizophrenia treatment patch Secuado<sub>®</sub> (Development code: HP-3070) in the U.S.
- Jun. Approval for manufacturing and marketing approval of the additional indications of cancer pain relief for opioid analgesic naive patients of Fentos<sub>®</sub> Tape (Transdermal, pain management patch, Development code: HFT-290) in Japan.
- Jul. •Application for partial change of manufacturing and marketing approval of Mohrus<sub>®</sub> Pap XR 120mg, 240mg (Topical analgesic and anti-inflammatory products) in Japan.
- Jul. ·Approval for manufacturing and marketing approval of OABLOK<sub>®</sub> PATCH (Transdermal, Overactive bladder treatment patch) in Thailand.
- Sep. ·Application for manufacturing and marketing approval of the additional indications of cancer pain relief for pediatric patients of Fentos<sub>®</sub> Tape (Transdermal, pain management patch, Development code: HFT-290) in Japan.
- Oct. Commencement of the Phase III clinical study of HP-5070 (a primary palmar hyperhidrosis treatment drug) in Japan.
- Dec. •Completion of the Phase Ⅲ clinical study of HP-3150 for "low back pain, humeroscapular periarthritis, cervico-omo-brachial syndrome and tenosynovitis" in Japan (Transdermal, pain treatment NSAID patch)
- Dec. · Launch of Rivastigmine Tapes "Hisamitsu" in Japan (Transdermal, patches for the Treatment of Alzheimer's Disease)
- Jan. · Commencement of the Phase III clinical study of HP-5000 in the U.S. (Transdermal, pain relief and anti-inflammatory patch)
- Jan. Approval for partial change of manufacturing and marketing approval of Mohrus, Pap XR 120mg, 240mg (Topical analgesic and anti-inflammatory products) in Japan.
- Feb Noven submits new drug application for investigational dextroamphetamine transdermal system for ADHD

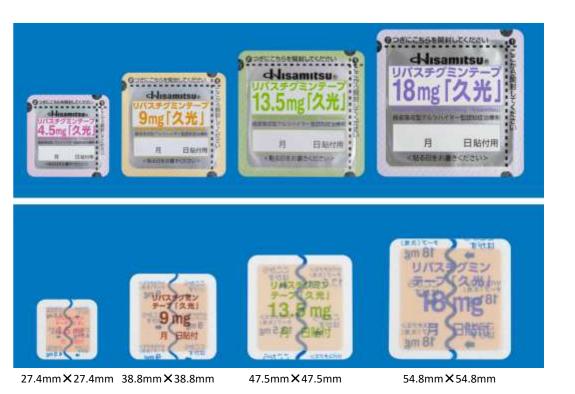
Business

Rx

\*Mar. 23<sup>rd</sup> Approval for manufacturing and marketing approval of ZICTHORU<sub>®</sub> Tapes for "cancer pain" in Japan (Transdermal, pain treatment NSAID patch, Development code: HP-3150)

# 1. Looking back on the FY02/2021 (2)

Rivastigmine Tapes "Hisamitsu" (Transdermal, patches for the treatment of Alzheimer's Disease)



ZICTHORU<sub>®</sub> Tapes 75mg (Transdermal, dicrofenac sodium patches for cancer pain)



# 1. Looking back on the FY02/2021 (3)

	Apr. Jun.	<ul> <li>Renovation of Butenalock<sub>®</sub> L powder gel.</li> <li>Launch of Air<sub>®</sub> Salonpas<sub>®</sub> Z.</li> </ul>
OTC		·
Business	Aug.	• Launch of Salonpas <sub>®</sub> Tsubokori <sub>®</sub> Patch.
	Jan.	• Renovation of Feitas • 5.0 "Hot Type".
	Feb.	•Renovation of Feitas <sub>®</sub> 5.0 & Feitas <sub>®</sub> 5.0 "Large Size".
	*Mar.	16 <sup>th</sup> Renovation of Feitas <sub>®</sub> 5.0 "Hot Type, Large Size".
	Mar.	• Establishment of "SAGA HISAMITSU SPRINGS Co., Ltd" managing Hisamitsu Springs.
	Mar.	<ul> <li>Launch of Butenalock<sub>®</sub> medicated soap 150g new package.</li> </ul>
	Apr.	<ul> <li>Certification acquisition of the cooperative energy saving plan in the Smart Energy Networks Project in the Kiyohara Industrial Complex</li> </ul>
	May.	•The "MAKE IT BLUE Campaign" to express gratitude to the healthcare workers by lighting up in blue.
	-	■ Salonpas <sub>®</sub> named the World's No. 1 OTC Topical Analgesic Patch Brand for the 4 <sup>th</sup> consecutive years.
	Aug.	
Others	Aug.	<ul> <li>Providing relief supplies in response to 2020 Kyushu floods.</li> </ul>
	Aug.	Concluded a partnership agreement with Tosu City.
	Sep.	■ Launch of Hisamitsu <sub>®</sub> BODYCARE series.
	Oct.	Providing Air <sub>®</sub> Salonpas to the member organizations of the Japan Olympic Committee (JOC).
	Oct.	Providing Air <sub>®</sub> Salonpas to the member organizations of the Japan Paralympic Committee (JPC).
	Oct.	• Launch of Hisamitsu <sub>®</sub> Vitality Amino Acid <sub>®</sub> DX series.
	Dec	·Launch of Hisamitsu <sub>®</sub> Sanitizer-Antibacterial-Deodorant Spray.
	Feb	•Receiving a Director Prize 2020 of the cooperative energy saving plan in the Smart Energy Networks
		Project in the Kiyohara Industrial Complex
	*Mar 3	31st Establishment the ecology mark and the website regarding "HELLO! Eco!".

<sup>\*</sup>Mar. 31st Establishment the ecology mark and the website regarding "HELLO! Eco!".

<sup>\*</sup>Apr. 2<sup>nd</sup> Donation to Japanese Olympic Committee (JOC) and Japanese Paralympic Committee (JPC).

# 1. Looking back on the FY02/2021 (4)



1. Feitas<sub>®</sub>5.0



2. Feitas<sub>®</sub>5.0 "Large Size"



3. Feitas<sub>®</sub>5.0 "Hot Type"



4. Feitas<sub>®</sub>5.0 "Hot Type, Large Size"





**Size Reduction** 

Horizonal: 11mm, Vertical: 17mm

Expected benefits of ecology and compact packaging

CO<sub>2</sub> emissions reduction: 3.1t/ year Waste emissions reduction: 6.9t/ year

# 1. Looking back on the FY02/2021 (5)

Activities in preparation for the Olympic and Paralympic games Tokyo 2020.

### Renewal of the Tokyo 2020 special site

We singed the agreement of "Tokyo 2020 Official Partner" (External Pain Relief Products) on February 6<sup>th</sup>, 2018. And we have renewed "HISAMITSU TOKYO 2020 SPECIAL SITE" from February 6, 2021 (this day is the 4th year anniversary).



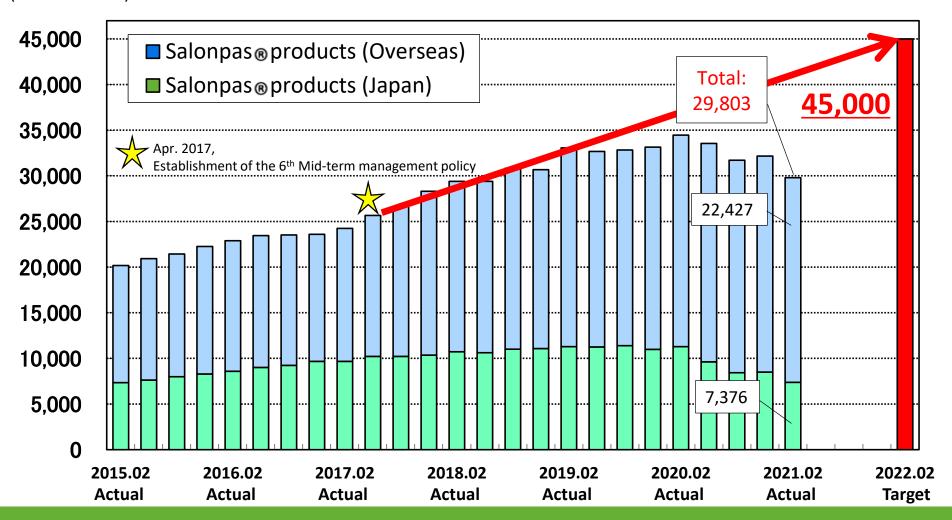
Hisamitsu supports the Tokyo 2020 Olympic and Paralympic games as Tokyo 2020 Official Partner (External Pain Relief Products)

## 1. Looking back on the FY02/2021 (6)

[Sales transition of Salonpas<sub>®</sub> products]

Target: Annual sales of 45 billion yen (for the FY02/2022)

(MAT: ¥ Million)



### 2. Promotion of ESG (1)

### Smart Energy Networks Project in the Kiyohara Industrial Complex

### [Receiving a Director Prize 2020 of the cooperative energy saving plan ]

The Smart Energy Networks Project in the Kiyohara Industrial Complex was evaluated for its advanced approach and won the prime director Prize of the cooperative energy saving plan.



\*This is an institution in which the Advanced Cogeneration and Energy Utilization Center Japan awards excellent cogeneration systems in terms of novelty, leadership, new technology and energy conservation. [ Reduction effect of cooperation between 3 companies ] Energy Reduction Rate: 20% CO<sub>2</sub> Reduction Rate: 20%

\*Reduction rate of electricity and the heat sent by the energy center mainly composed of cogeneration systems.

(Comparison between 2015 and 2020)

[ Redction effect of Hisamitsu ] Energy Reduction Amount & Rate:  $965 \text{k} \ell$  24.2% CO<sub>2</sub> Reduction Amount & Rate: 1,578t 21.0%

\* (Comparison between 2019 and 2020)

## 2. Promotion of ESG (2)

### Reinforcement of the sustainability promotion system

- Establishment of the Sustainability Promotion Committee (Jan, 2021)
- Establishment of the Sustainability Promotion Department (Mar, 2021)

### Web site establishment of "HELLO! eco!"

We set the slogan as "HELLO! eco!" in order to sustain our environmental load reduction activities.

# "HELLO! Eco!" mark HELLO! OCUMENTAL NOTE: NOTE:



### "HELLO! Eco!" website



# 3. Consolidated P&L (1) - Comparison with the previous period performance -

					Unit:¥ Million
	Actual for FY02/2020	Actual for FY02/2021	Difference	Percentage Change	Forecast * for FY02/2021
Net Sales	140,992	114,510	-26,481	-18.8%	115,000
COGs	53,388	45,337	-8,051	-15.1%	45,500
as a % of Net Sales	37.9%	39.6%			39.5%
SG&A Costs	64,875	58,501	-6,374	-9.8%	58,900
Sales Promotion Costs	13,873	13,466	-406	-2.9%	13,500
Advertising Costs	14,758	11,259	-3,499	-23.7%	11,300
R&D Costs	10,504	10,766	+262	+2.5%	10,800
Others	25,739	23,008	-2,730	-10.6%	23,300
Operating Profits	22,727	10,671	-12,056	-53.0%	10,600
Recurring Profits	25,628	11,829	-13,799	-53.8%	11,900
Net Profits	18,694	9,250	-9,443	-50.5%	9,300
Exchange Rate (JPY/USD)	109.24	106.43			*Published on Mar. 23 <sup>rd</sup> , 2021

# 3. Consolidated P&L (2) – Summary of Profit and Loss -

	Actual for FY02/2020	Actual for FY02/2021	Difference	Main Factor
Net Sales	140,992	114,510	-26,481	
COGs	53,388	45,337	-8,051	
as a % of Net Sales	37.9%	39.6%		• Affected by the drug price revision in Japan. • [FY02/2020] Sales recognition of the milestone payment on approval.
SG&A Costs	64,875	58,501	-6,374	
Sales Promotion Costs	13,873	13,466	-406	<ul> <li>Increased of costs associated with launch of Secuado.</li> <li>Stagnation of sales promotion activities because of COVID-19.</li> </ul>
Advertising Costs	14,758	11,259	-3,499	• Cancellations of the events such as World Ladies Champion Ship Salonpas Cup.
R&D Costs	10,504	10,766	+262	Reduction of costs due to completion of Phase 3 clinical study of HP-3150 (cancer pain). Increased of costs related to Phase 3 clinical study of HP-3150 (low back pain).
Others	25,739	23,008	-2,730	• Reduction of costs associated with refraining from sales promotion
Operating Profits	22,727	10,671	-12,056	
Non-Operating Balance	2,901	1,158	-1,742	<ul> <li>Increased Share of profit of entities accounted for using equity method.</li> <li>Increased foreign exchange losses.</li> </ul>
Recurring Profits	25,628	11,829	-13,799	
Extraordinary Balance	526	367	-158	• [FY02/2020] Settlement received. • [FY02/2020] Impairment loss.
Net Profits	18,694	9,250	-9,443	

# 4. Sales Results by Region

		Actual for FY02/2020	Actual for FY02/2021	Difference	Percentage Change
Net Sales		140,992	114,510	-26,481	-18.8%
	Japan	65,080	52,181	-12,899	-19.8%
Rx Business	USA	12,262	10,169	-2,092	-17.1%
	Other Regions	4,036	3,715	-321	-8.0%
	Japan	29,682	20,239	-9,443	-31.8%
OTC Business	USA	12,103	12,087	-16	-0.1%
	Other Regions	15,186	13,367	-1,818	-12.0%
Others	Japan	2,640	2,749	+109	+4.1%

# 5. Sales Results by Product (1) - Rx Business -

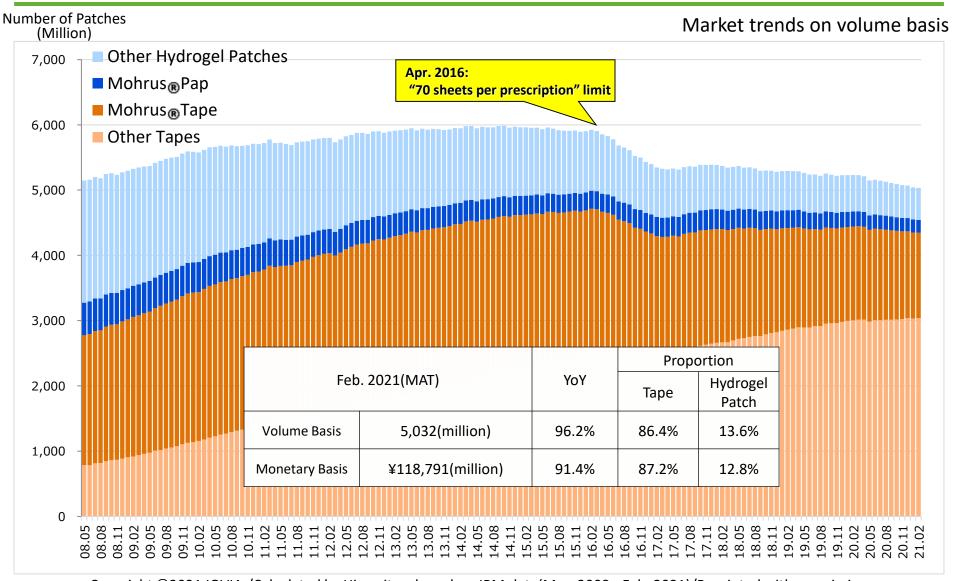
	Actual for FY02/2021			
	Total	Japan	Overseas	
Rx Business	66,066	52,181	13,885	
Fentos <sub>®</sub> Tape	3,569	3,569	-	
Neoxy <sub>®</sub> Tape	500	500	-	
Abstral®	205	205	-	
Allesaga®Tape	291	291	-	
Haruropi₀Tape	1,185	1,185	-	
Mohrus <sub>®</sub> Tape	33,450	33,073	377	
Mohrus <sub>®</sub> Pap	5,125	5,125	-	
(Mohrus <sub>®</sub> Pap XR)	3,774	3,774	-	
Others	8,232	7,136	1,095	
Minivelle <sup>®</sup> products	2,510	ı	2,510	
Vivelle-Dot <sup>®</sup> products	3,778	1	3,778	
CombiPatch <sup>®</sup> products	4,882	1,093	3,789	
Daytrana®	2,183	-	2,183	
Secuado <sub>®</sub>	148	-	148	

	Difference		Percentage Change			
Total	Japan	Overseas	Total	Japan	Overseas	
-15,313	-12,899	-2,414	-18.8%	-19.8%	-14.8%	
-585	-585	-	-14.1%	-14.1%	-	
-104	-104	1	-17.2%	-17.2%	-	
+7	+7	1	+3.6%	+3.6%	-	
-65	-65	1	-18.4%	-18.4%	-	
+511	+511	-	+75.9%	+75.9%	-	
-5,641	-5,412	-228	-14.4%	-14.1%	-37.7%	
-1,282	-1,282	-	-20.0%	-20.0%	-	
-885	-885	-	-19.0%	-19.0%	-	
-6,557	-6,511	-45	-44.3%	-47.7%	-4.0%	
-738	-	-738	-22.7%	-	-22.7%	
-1,138	-	-1,138	-23.2%	-	-23.2%	
+546	+544	+2	+12.6%	+99.4%	+0.1%	
-307	-	-307	-12.3%	-	-12.3%	
+148	-	+148	_	_	-	

# 5. Sales Results by Product (2) - OTC Business -

	Actual for FY02/2021		Difference			Percentage Change			
	Total	Japan	Overseas	Total	Japan	Overseas	Total	Japan	Overseas
OTC Business	45,693	20,239	25,454	-11,277	-9,443	-1,834	-19.8%	-31.8%	-6.7%
Salonpas <sub>®</sub> products	29,803	7,376	22,427	-4,652	-3,913	-738	-13.5%	-34.7%	-3.2%
Salonsip <sub>®</sub> products	3,224	2,067	1,157	-763	-299	-464	-19.2%	-12.7%	-28.6%
Air <sub>®</sub> Salonpas <sub>®</sub> products	1,493	848	644	-208	-177	-31	-12.3%	-17.3%	-4.6%
Feitas <sub>®</sub> products	4,582	4,582	0	-1,332	-1,332	+0	-22.5%	-22.5%	-
Butenalock <sub>®</sub> products	1,311	1,311	-	-371	-371	-	-22.1%	-22.1%	-
Allegra <sup>®</sup> FX	2,255	2,255	-	-3,048	-3,048	-	-57.5%	-57.5%	-
Others	3,022	1,797	1,224	-900	-299	-601	-23.0%	-14.3%	-32.9%

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



# **7. R&D Pipeline (1)**

	Stage	Theme	Target	Dosage Form	Characteristics	Next Step
1	Approved	HP-1010	USA	Patch	Relief of pain associated with post-herpetic neuralgia	No disclosure
2	Approved	HP-3150	JPN	Patch	Cancer pain	To be launched in FY2021
3	Filed	<b>HFT-290</b> (Pediatric cancer pain patients)	JPN	Patch	Cancer pain	To be approved in FY2021
4	NDA Submitted	ATS	USA	Patch	Attention Deficit Hyperactivity Disorder(ADHD)	To be approved in FY2021
5	Filed being prepared	HP-3150	JPN	Patch	Low back pain Humeroscapular periarthritis Cervico- omo-brachial syndrome Tenosynovitis	To be filed in FY2021
6	Phase3	HP-5070	JPN	Transdermal	Primary palmar hyperhidrosis	To be filed in FY2022
7	Phase3	HP-5000	USA	Patch	Osteoarthritis of the knee	To be filed in FY2023

XYellow-highlighted parts are changes from the previous announcement made on Jan.13<sup>th</sup>,2021

## 7. R&D Pipeline (2)

### **ZICHTHORU**<sub>®</sub> Tapes

### **Transdermal Tapes for Cancer Pain**





- Active ingredient: Diclofenac sodium
- Indication: Analgesia in various cancers
- Dosage and Administration: Apply two ZICHTHORU® Tapes once daily. May increase dosage to three patches depending on patient symptom and condition

がん疼痛のある患者に対して、NSAIDsの投与は推奨されるか?

### 【推奨】

がん疼痛(軽度)のある患者に対して、NSAIDsの投与(初回投与)を推 奨する。(1B:強い推奨、中等度の根拠に基づく)

### 【推奨】

オピオイドが投与されているにもかかわらず、適切な鎮痛効果が得られていない、がん疼痛のある患者に対して、オピオイドとNSAIDsの併用を条件付きで推奨する。(2C:弱い推奨、弱いの根拠に基づく)

\* オピオイドが投与されているにもかかわらず、十分な鎮痛効果が得られない、または有害作用のため、オピオイドを増量できないとき。

かん疼痛の薬物療法に関するガイドライン(2020年版)

- 1. World's first transdermal NSAIDs tapes (patches)
- 2. Contain 75 mg diclofenac sodium by Hisamitsu formulation technology (5 times higher than existing Hisamitsu diclofenac topical tape (Naboal tape))
- Maintain steady plasma concentration by once daily application and expect sustained efficacy
- 4. Can be administered to patients with nausea, vomiting, dysphagia, gastrointestinal obstruction.
- NSAIDs is recommended as an introductory treatment for mild cancer pain and concomitant medication with opioid products for moderate to severe cancer pain (see table on the left)
- 6. No need for product management and control such as opioids.

To be filed for low back pain, humeroscapular periarthritis, cervico-omo-brachial syndrome and tenosynovitis in FY2021

# Outlook for the FY02/2022

### The main premise for outlook

- Domestic demand in each country will recover gradually toward the end of the current period.
- There are far fewer foreign visitors to Japan in FY02/2022 compared to the number of foreign visitors to Japan in the past years.

# 8. Forecast of Consolidated P&L

	Actual for FY02/2021	Forcast for FY02/2022	Difference	Percentage Change
Net Sales	114,510	122,900	+8,390	+7.3%
COGs	45,337	48,700	+3,363	+7.4%
as a % of Net Sales	39.6%	39.6%		
SG&A Costs	58,501	63,500	+4,999	+8.5%
Sales Promotion Costs	13,466	15,600	+2,134	+15.8%
Advertising Costs	11,259	12,100	+841	+7.5%
R&D Costs	10,766	11,300	+534	+5.0%
Others	23,008	24,500	+1,492	+6.5%
Operating Profits	10,671	10,700	+29	+0.3%
Recurring Profits	11,829	12,700	+871	+7.4%
Net Profits	9,250	9,900	+650	+7.0%
Exchange Rate (JPY/USD)	106.43	105.00		

# 9. Forecast of Sales by Region

		Actual Forecast for FY02/2021 for FY02/2022		Difference	Percentage Change
Net Sales		114,510	122,900	+8,390	+7.3%
	Japan	52,181	51,400	-781	-1.5%
Rx Business	USA	10,169	9,300	-869	-8.5%
	Other regions	3,715	4,300	+585	+15.7%
	Japan	20,239	26,200	+5,961	+29.5%
OTC Business	USA	12,087	12,500	+413	+3.4%
	Other regions	13,367	16,200	+2,833	+21.2%
Others	Japan	2,749	3,000	+251	+9.1%

# 10. Forecast of Sales by Product (1) - Rx Business -

	Forecast for FY02/2022		
	Total	Japan	Overseas
Rx Business	65,000	51,400	13,600
Fentos <sub>®</sub> Tape	3,300	3,300	-
Neoxy <sub>®</sub> Tape	600	600	-
Abstral®	200	200	-
Allesaga <sub>®</sub> Tape	500	500	-
Haruropi <sub>®</sub> Tape	3,300	3,300	-
Mohrus <sub>®</sub> Tape	30,400	29,800	600
Mohrus <sub>®</sub> Pap	4,600	4,600	-
(Mohrus <sub>®</sub> Pap XR)	3,300	3,300	-
Others	9,300	8,000	1,300
Minivelle® products	1,600	-	1,600
Vivelle-Dot® products	4,100	-	4,100
CombiPatch® products	4,700	1,100	3,600
Daytrana®	1,800	-	1,800
Secuado <sup>®</sup>	600	_	600

	Difference		Percentage Change			
Total	Japan	Overseas	Total	Japan	Overseas	
-1,067	-781	-285	-1.6%	-1.5%	-2.1%	
-270	-270	-	-7.6%	-7.6%	-	
+99	+99	-	+19.8%	+19.8%	-	
-6	-6	-	-2.8%	-2.8%	-	
+209	+209	-	+71.7%	+71.7%	-	
+2,114	+2,114	-	+178.3%	+178.3%	-	
-3,051	-3,273	+222	-9.1%	-9.9%	+58.9%	
-525	-525	-	-10.2%	-10.2%	-	
-474	-474	-	-12.6%	-12.6%	-	
+1,089	+888	+201	+13.3%	+12.5%	+18.5%	
-911	-	-911	-36.3%	-	-36.3%	
+321	-	+321	+8.5%	-	+8.5%	
-183	+7	-190	-3.7%	+0.6%	-5.0%	
-383	-	-383	-17.6%	-	-17.6%	
+452	-	+452	+304.8%	-	+304.8%	

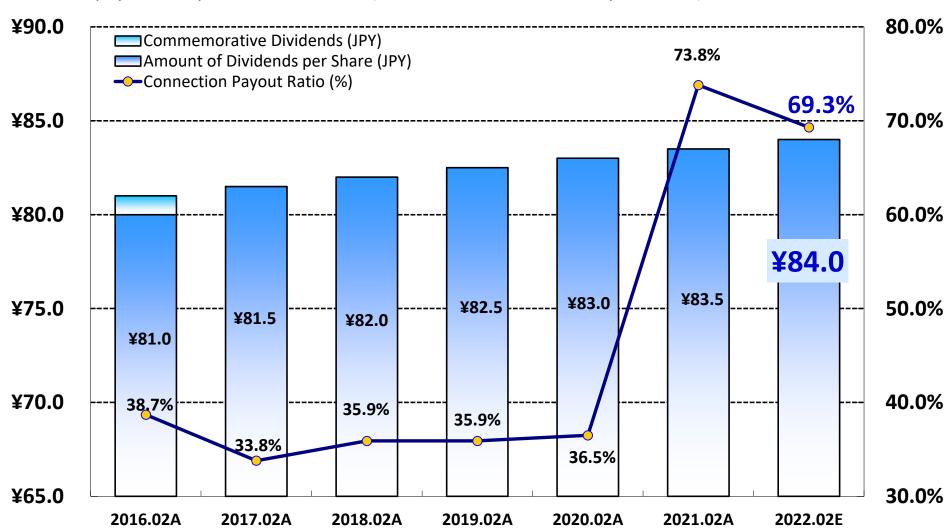
# 10. Forecast of Sales by Product (2) – отс Business -

	Forecast for FY02/2022			
	Total	Japan	Overseas	
OTC Business	54,900	26,200	28,700	
Salonpas <sub>®</sub> products	33,000	8,100	24,900	
Salonsip <sub>®</sub> products	3,600	2,400	1,200	
Air <sub>®</sub> Salonpas <sub>®</sub> products	1,800	1,100	700	
Feitas <sub>®</sub> products	5,240	5,200	40	
Butenalock <sub>®</sub> products	1,800	1,800	-	
Allegra <sup>®</sup> FX	4,500	4,500	-	
Others	4,960	3,100	1,860	

Difference			Percentage Change		
Total	Japan	Overseas	Total	Japan	Overseas
+9,206	+5,961	+3,245	+20.1%	+29.5%	+12.7%
+3,196	+723	+2,473	+10.7%	+9.8%	+11.0%
+375	+333	+43	+11.6%	+16.1%	+3.7%
+307	+252	+55	+20.6%	+29.7%	+8.6%
+657	+618	+39	+14.3%	+13.5%	+7479.6%
+488	+488	-	+37.2%	+37.2%	ı
+2,245	+2,245	-	+99.5%	+99.5%	-
+1,937	+1,302	+635	+64.1%	+72.4%	+51.9%

### 11. Forecast of Dividend

For the term ending Feb. 2022, the consolidated dividend payout ratio is predicted to be 69.3% and the payout is expected to be ¥84.0. (\*Mid-term dividend ¥42.0 predicted.)



# Patch, moving into the future.







Tokyo 2020 Official Partner (External Pain Relief Products)



For muscle ache, muscle fatique Third-class OTC drugs



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



For stiff shoulders, shoulderache, backache For muscle ache, muscle fatigue Second-class OTC drugs



Third-class OTC drugs