# Hisamitsu Pharmaceutical Co., Inc. Q3 FY02/2022 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. 13th, 2022

# **Agenda**

- 1. Looking back on the Q3 FY02/2022
- 2. Promotion of ESG
- 3. Progress for FY02/2022
- 4. Consolidated P&L
- 5. Sales Results by Region
- 6. Sales Results by Product
- 7. Trends of 2nd-generation non-steroidal anti-inflammatory patch in Japan
- 8. R&D Pipeline

#### 1. Looking back on the Q3 FY02/2022(1)

	<ul> <li>Mar. •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)</li> <li>Apr. •Results of the Phase Ⅲ clinical study of HP-5070 in Japan. (Primary palmar hyperhidrosis treatment drug)</li> <li>May •Marketing of ZICTHORU<sub>®</sub> Tapes for "cancer pain" in Japan (Transdermal, pain treatment</li> </ul>
Rx	NSAID patch)
Business	Jul. •Transfer of Marketing Rights for ORAVI® Mucoadhesive Tablets 50mg for Oropharyngeal Candidiasis Aug. •Application for manufacturing and marketing approval of the additional indications of "low back pain, humeroscapular periarthritis, cervico-omo-brachial syndrome and tenosynovitis" for ZICTHORU® Tapes(Transdermal, pain treatment NSAID patch, development code: HP-3150) in Japan Aug. •Approval for manufacturing and marketing approval of the additional indications of cancer pain relief for pediatric patients of FENTOS® Tapes (Transdermal, pain management patch,
	Development code: HFT-290) in Japan

#### OTC Business

Mar. • Launch of renewal Feitas<sub>®</sub> 5.0 "Hot Type and Large Size"

Aug. • Launch of new package "Nobinobi<sub>®</sub> Salonsip<sub>®</sub> Fit<sub>®</sub>", 10 patchesNickname: "Poke-Sip"

Sep. • Launch of a Food with Functional Claims, "Hisamitsu<sub>®</sub> ARU-KANTO<sub>®</sub>" in Japan

Oct. • Hisamitsu Pharmaceutical Online Sales "Hisamitsu<sub>®</sub> Iki-Iki Online", Announcement of Starting Pharmaceutical Product Sales in Japan

Oct. Launch of Mask Made of Non-Woven Fabric Used for Hydrogel Patch in Japan

#### 1. Looking back on the Q3 FY02/2022(2)

Hisamitsu<sub>®</sub> ARU-KANTO<sub>®</sub>





[Functional Food]

Mask Made of Non-Woven Fabric Used for Hydrogel Patch





[Ear Wearable Mask] [Adhesive Mask]

#### 1. Looking back on the Q3 FY02/2022(3)

- Mar. Establishment the Ecology Mark and the Website Regarding "HELLO! Eco!"
- Apr. Donation to Japanese Olympic Committee (JOC) and Japanese Paralympic Committee (JPC)
- May •Salonpas® Named the World's No. 1 OTC Topical Analgesic Patch Brand for the 5<sup>th</sup> Consecutive Years
- May Conclusion of Cooperation Agreement with Saga Prefecture and Saga Sports Association
- Aug. •Hisamitsu Pharmaceutical Co., Inc. receiving Administrative Disposition from Saga Prefecture
- Aug. Honorary Chairman Passes Away

#### Others

- Aug. Providing Relief Supplies in Response to The Torrential Rains in August 2021
- Aug. Support for The Disaster of The Torrential Rains in August 2021
- Sep. Establishment of "the 7th Medium-term Management Policy"
- Sep. Investment in GAIA Biomedicine, a Bio-Venture from Kyushu University in Japan
- Oct. Regarding Concerning the Decision of Matters Relating to Acquisition of Company's Own Shares
- Oct. Regarding Application for Selection of "Prime Market" Under the New Market Segments
- Nov. Products to solve issues for living in Space and living on Earth "Fixpace<sub>®</sub>" Notification to be used in the International Space Station
- \*Dec. 1st: Donation to Japanese Olympic Committee (JOC) and Japanese Paralympic Committee (JPC)

**Fixpace** 

\*Dec. 20<sup>th</sup>: RaQualia Pharma and Hisamitsu Pharmaceutical have agreed to enter into a license agreement for a novel sodium channel blocker

Fixpace<sub>®</sub>

#### 1. Looking back on the Q3 FY02/2022(4)

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

#### Donation to Japanese Olympic Committee (JOC) and Japanese Paralympic Committee (JPC)

[Donation]

- 1. Japanese Olympic Committee (JOC)
- 2. Japanese Paralympic Committee (JPC)

[Date] Nov. 30, 2021

[Amount of money] ¥2.465.370

"Energize Japan! Hisamitsu original campaign to support Tokyo 2020"



Masaya Okuno (Executive Officer Head of Sales & Marketing Japanese Olympic Division, OTC of Hisamitsu Pharmaceutical Co., Inc.)

"Catalog of donation"

(President of the

Committee)



Yasuhiro Yamashita Masaya Okuno (Executive Officer Head of Sales & Marketing Division, OTC of Hisamitsu

Pharmaceutical Co., Inc.)



Hisamitsu original campaign ("Energize Japan! to support Tokyo 2020" (from Jun. 1, 2021 to Sep. 30, 2021)) received 246,537 applications. 1 application was converted into ¥10 and delivered donations.

\*The contribution will be used for a meeting and the activity that a competition group has.

Hisamitsu contribute to making the promotion of sports and the health of people through various activities in future

# 2. Promotion of ESG(1)

Materiality (Important issues)	KPI
Promoting "patch treatment culture" worldwide and creating	Expansion of the number of countries and regions where our products are sold
products and services with enthusiasm for "TE-A-TE"	Promoting drug improvement in consideration of the environment and ease of use (drug improvement: product improvement, additional indications, etc.)
~₩ <b>`</b>	Creation of products and services filled with the spirit of care (therapeutic patches and other products and services that are filled with the spirit of care)
	Reduction of CO₂ emissions (Scopes 1 and 2)  Reduce by 46% from FY 2013 by 2030.  Target: All domestic bases
Promoting environmental management	Waste reduction  1) Reduce industrial waste discharged by plants Disposal rate by 1.5% from FY 2020 by FY 2025 *Disposal rate = Amount of industrial waste / total amount of production  2) Reduce "household waste" in accordance with the Containers and Packaging Recycling Law Reduce by 10% from FY 2020 by FY 2030 *Excluding the effect of increase/decrease in sales volume.
	Sustainability procurement survey answer rate  Implementation and response rate of 100% by FY 2025.  Targets: primary suppliers, secondary suppliers  *Primary suppliers: Suppliers from which we purchase raw materials used for our manufacturing  *Secondary suppliers: Manufacturers of raw materials used in our products with which we are not in a direct contractual relationship
Supplying high-quality products and	Zero product recalls Achieve annual product recall rate of zero.
services 12 Yes Rd	Product complaint rate  Achieve product complaint rate of not more than 0.001% by FY 2025.  Target: Product-related complaints about all products manufactured and sold by our company
Promoting D&I and work style	Morale Surveillance Score (8 relevant items: motivation + ease of working)  Achieve mean value for 8 items of 5.0 P or higher by FY 2025.
reform 5 Sany and 8 styre 8 styre	Percentage of female managers Increase to 1.5 times as high as at the end of March 2021 by March 31, 2024.
<b>₽</b>	Percentage of female employees who continues employment with our company 9 to 11 years after joining  Achieve continued employment rate of 45% or more by March 31, 2024.

#### 2. Promotion of ESG(2)

#### Reduce CO<sub>2</sub> emissions

Installation of a new solar power generation system at the Kyushu headquarters (October, 2021)



CO<sub>2</sub> emissions
Reduction of approx.
88 tons/year

Example: Future capital investment

- Air conditioner replacement
- Air conditioning control modification

#### 2. Promotion of ESG(3)

#### Eco-activity in the business activities in Japan

Promotion of "ecodrive 10" (September, 2021 -)

\*The ecodrive spread Network devised it in Ministry of Economy, Trade and Industry, the Ministry of Land, Infrastructure, Transport and Tourism, Ministry of the Environment, the National Police Agency



Automotive sticker Seal for the driver



- ①自分の燃費を把握しよう
- ②ふんわりアクセル「eスタート」
- ③車間距離にゆとりをもって、 加速・減速の少ない運転
- ④減速時は早めにアクセルを離そう
- ⑤エアコンの使用は適切に
- ⑥ムダなアイドリングはやめよう
- ⑦渋滞を避け、余裕をもって出発しよう
- ⑧タイヤの空気圧から始める点検・整備
- 9不要な荷物はおろそう
- 10走行の妨げとなる駐車はやめよう

**SDGs Target** 





#### **3. Progress for FY02/2022**

**Unit:**¥ Million

Consolidated P&L	Q3 FY02/2022	FY02/2022		
	Actual	Forecast	Progress Rate	
Net Sales	86,663	122,900	70.5%	
<b>Operating Profits</b>	6,973	10,700	65.2%	
Ordinary Profit	8,665	12,700	68.2%	
Net Profits	6,218	9,900	62.8%	

\*There is no change in the earnings forecast.

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

	Actual performance for FY02/21 (Q3)	Actual performance for FY02/22 (Q3)	Change	Percentage Change
Net sales	80,822	86,663	+5,841	+7.2%
CoGS	30,148	34,884	+4,736	+15.7%
as a % of sales	37.3%	40.3%		
SG&A costs	42,551	44,805	+2,254	+5.3%
Sales promotion costs	9,583	10,789	+1,206	+12.6%
Advertising costs	8,288	8,465	+176	+2.1%
R&D costs	7,873	7,455	-417	-5.3%
Others	16,806	18,094	+1,288	+7.7%
Operating profits	8,123	6,973	-1,150	-14.2%
Ordinay Profit	7,928	8,665	+736	+9.3%
Net profits	5,722	6,218	+495	+8.7%
Exchange Rate (JPY/USD)	107.3	109.1		

## 4. Consolidated P&L (2) - Summary of Profit and Loss 1 -

	Actual performance for FY02/21 (Q3)	Actual performance for FY02/22 (Q3)	Change	Main factor
Net sales	80,822	86,663	+5,841	
CoGS	30,148	34,884	+4,736	
as a % of sales	37.3%	40.3%		<ul><li>Affected by the drug price revision in Japan.</li><li>Change of sales mix.</li></ul>
SG&A costs	42,551	44,805	+2,254	
Sales promotion costs	9,583	10,789	+1,206	<ul> <li>Increase in aggressive domestic and international sales promotion activities</li> </ul>
Advertising costs	8,288	8,465	+176	
R&D costs	7,873	7,455	-417	• [FY02/2021]Expenses of Phase 3 clinical study of HP-3150 (low back pain). • [FY02/2022]Expenses of Phase 3 clinical study of HP-5000.
Others	16,806	18,094	+1,288	•Increase in logistics costs
Operating profits	8,123	6,973	-1,150	
Nonoperating balance	-194	1,692	+1,886	• [FY02/2021]Foreign exchange loss. • [FY02/2022]Foreign exchange gain.
Ordinary Profit	7,928	8,665	+736	
Extraordinary balance	334	326	-7	
Net profits	5,722	6,218	+495	

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

	Q	Q1 FY02/2022 Q2 FY02/2022 Q3 FY02/2022		Q2 FY02/2022		22			
Consolidated P&L	FY02/21	FY02/22	Percentage Change	FY02/21	FY02/22	Percentage Change	FY02/21	FY02/22	Percentage Change
Net sales	24,882	27,761	+11.6%	28,043	30,789	+9.8%	27,896	28,112	+0.8%
CoGS	9,672	11,162	+15.4%	9,904	11,958	+20.7%	10,570	11,763	+11.3%
as a % of sales	38.9%	40.2%		35.3%	38.8%		37.9%	41.8%	
SG&A costs	14,132	14,479	+2.5%	13,701	15,244	+11.3%	14,718	15,081	+2.5%
SG&A % of sales	56.8%	52.2%		48.9%	49.5%		52.8%	53.6%	
Sales promotion costs	3,032	3,574	+17.9%	2,850	3,581	+25.6%	3,700	3,660	-1.1%
Advertising costs	2,661	2,670	+0.3%	2,865	3,039	+6.1%	2,761	2,754	-0.3%
R&D costs	2,676	2,586	-3.4%	2,563	2,425	-5.4%	2,632	2,444	-7.1%
Others	5,761	5,674	-1.5%	5,421	6,198	+14.3%	5,623	6,222	+10.7%
Operating profits	1,078	2,120	+96.7%	4,437	3,586	-19.2%	2,607	1,266	-51.4%
Ordinary Profit	418	2,855	+583.0%	5,101	3,981	-22.0%	2,409	1,828	-24.1%
Net profits	113	2,362	+1990.3%	3,579	2,639	-26.3%	2,029	1,216	-40.1%

<sup>•</sup> Continue to invest in growth to achieve the policies set forth in the 7th Mid-term Management Policy

<sup>•</sup>Increase in implementation costs due to the adoption of the "Eco & Compact" package as an ESG initiative

# 5. Sales Results by Region

		Actual for FY02/21 (Q3)	Actual for FY02/22 (Q3)	Difference	Percentage Change
Net sales		80,822	86,663	+5,841	+7.2%
	Japan	38,816	41,040	+2,224	+5.7%
Dy Pusinosa	Overseas	9,500	9,999	+498	+5.2%
Rx Business	USA	7,247	6,780	-467	-6.4%
	Other regions	2,253	3,218	+965	+42.9%
	Japan	13,916	14,042	+125	+0.9%
OTC Puningg	Overseas	16,549	19,431	+2,882	+17.4%
OTC Business	USA	8,986	10,079	+1,092	+12.2%
	Other regions	7,562	9,352	+1,789	+23.7%
Others	Japan	2,039	2,149	+110	+5.4%

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

		al performa	
		r FY02/22 C	
	Total	Japan	Overseas
Rx Business	51,039	41,040	9,999
Fentos <sub>®</sub> Tape	2,745	2,745	-
Neoxy <sub>®</sub> Tape	356	356	-
Abstral <sup>®</sup>	154	154	-
Allesaga <sub>®</sub> Tape	284	284	-
Haruropi <sub>®</sub> Tape	2,512	2,512	-
Zicthoru <sub>®</sub> Tapes	155	155	-
Mohrus <sub>®</sub> Tape	24,097	23,797	300
Mohrus <sub>®</sub> Pap	3,736	3,736	-
(Mohrus <sub>®</sub> Pap XR)	2,805	2,805	-
Others	6,771	6,351	419
Minivelle <sup>®</sup> products	1,436	-	1,436
Vivelle-Dot <sup>®</sup> products	3,320	-	3,320
CombiPatch <sup>®</sup> products	3,728	944	2,784
Daytrana®	1,486	_	1,486
Secuado <sub>®</sub>	252		252

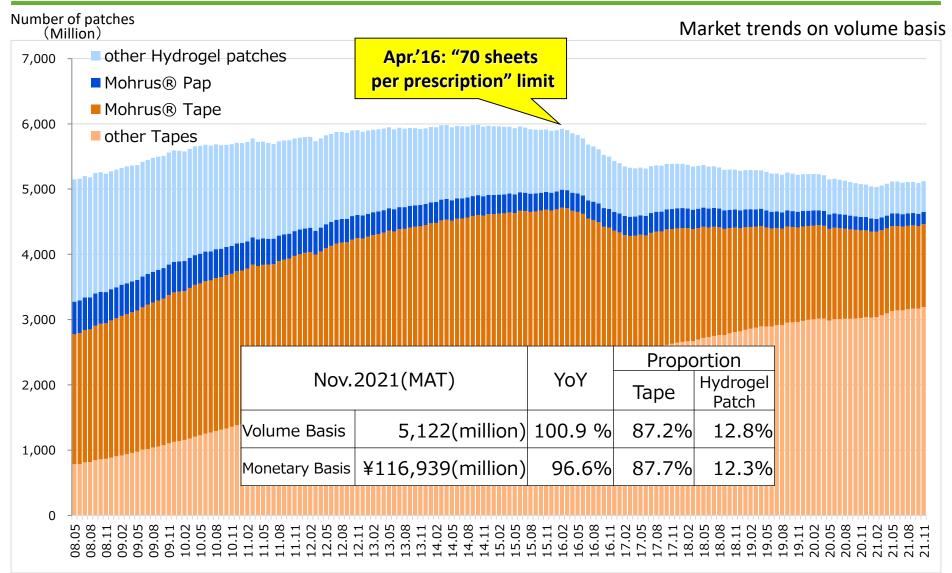
	Change		Perc	entage Cha	inge
Total Japan Ov		Overseas	Total	Japan	Overseas
+2,722	+2,224	+498	+5.6%	+5.7%	+5.2%
+69	+69	-	+2.6%	+2.6%	-
-0	-0	-	-0.2%	-0.2%	-
+1	+1	-	+0.7%	+0.7%	-
+136	+136	-	+91.7%	+91.7%	-
+1,669	+1,669	-	+198.1%	+198.1%	-
+155	+155	-	-	-	-
-768	-1,011	+242	-3.1%	-4.1%	+420.1%
-164	-164	-	-4.2%	-4.2%	-
-55	-55	-	-2.0%	-2.0%	-
+792	+1,224	-432	+13.3%	+23.9%	-50.7%
-342	-	-342	-19.2%	-	-19.2%
+868	-	+868	+35.5%	-	+35.5%
+288	+144	+144	+8.4%	+18.1%	+5.5%
-144	_	-144	-8.9%		-8.9%
+163	-	+163	+184.2%	-	+184.2%

# 6. Sales Results by Product (2) - отс Business -

	Actual performance for FY02/22 Q3			
	Total	Japan	Overseas	
OTC Business	33,474	14,042	19,431	
Salonpas <sub>®</sub> products	22,472	5,175	17,297	
Salonsip <sub>®</sub> products	2,426	1,759	667	
Air <sub>®</sub> Salonpas <sub>®</sub> products	1,051	658	393	
Feitas <sub>®</sub> products	3,293	3,273	20	
Butenalock <sub>®</sub> products	1,146	1,146	-	
Allegra <sup>®</sup> FX	827	827	-	
Others	2,254	1,201	1,053	

	Change		Perc	entage Cha	nge
Total	Japan	Overseas	Total	Japan	Overseas
+3,008	+125	+2,882	+9.9%	+0.9%	+17.4%
+1,943	-471	+2,415	+9.5%	-8.3%	+16.2%
+253	+153	+100	+11.7%	+9.5%	+17.8%
-92	-91	-1	-8.1%	-12.2%	-0.3%
-80	-100	+20	-2.4%	-3.0%	-
+98	+98	-	+9.4%	+9.4%	-
+724	+724	-	+696.9%	+696.9%	-
+160	-186	+346	+7.7%	-13.4%	+49.1%

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



Copyright ©2021 IQVIA./Calculated by Hisamitsu. based on JPM data(Jun.2007 ~ Nov.2021)/Reprinted with permission

#### 8. R&D Pipeline

	Stage	Theme	Target	Dosage Form	Characteristics	Next Step
1	Filed	ATS	USA	Patch	Attention Deficit Hyperactivity Disorder(ADHD)	To be approved in FY22
2	Filed	HP-3150	JPN		Low back pain Humeroscapular periarthritis Cervico- omo-brachial syndrome Tenosynovitis	To be approved in FY22
3	Filed being prepared	HP-5070	JPN	Transdermal	Primary palmar hyperhidrosis	To be filed in FY22
4	Phase3	HP-5000	USA	Patch	Osteoarthritis of the knee	To be filed in FY23

\*Yellow-highlighted parts are changes from the previous announcement made on Oct. 14th, 2021





Our commitments originate from each individual's determination to "start something good for ecology (eco)!"

Hisamitsu Pharmaceutical has designed the "HELLO! eco!" mark as a symbol of its environmental activities,

and products that have met the ecology standards that our company has established will display the "HELLO! eco!" mark sequentially.

