FY2024 Q2 Financial Results Presentation (From April 1, 2024 to September 30, 2024)

November 7, 2024 Mochida Pharmaceutical Co., Ltd.



Disclaimer (1/2)

- This material is an English translation of the Financial Results Presentation for the Fiscal Year 2024 Q2 to be issued on November 7, 2024 in Japanese, and the Japanese presentation is given priority regarding content and interpretation.
- The information provided in this material contains some "forward-looking statements". These forward-looking statements are based on the judgments of the Company derived from the information available to us at this time, and include known and unknown risks and uncertain elements. Accordingly, the actual results may differ materially from these statements due to a variety of factors.
- These risks and uncertainties include general economic conditions in Japan and worldwide, such as the general situation in the industry and markets, interest rates and currency exchange rate fluctuations. The risks and uncertainties exist in forward-looking statements relating to products in particular. These product-related risks and uncertainties include, but are not limited to, technological advancements, granting of patents to our competitors, completion of clinical trials, claims or concerns relating to safety or efficacy of products, acquisition of approval from regulatory authorities, reform of health insurance systems inside and outside Japan, trends toward the containment of health care cost, government law and regulations that affect the Company's business inside and outside Japan, and issues pertaining to development of new products.



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- We do not intend to, and assume no obligation to, update or modify any forward-looking statements even if such updating or modification is desirable due to the emergence of new information, future events or other reasons.
- The information contained in this material regarding pharmaceutical products (including those which are being developed) is not intended to act as a promotion or advertisement, or to provide medical advice.



Agenda

- FY2024 Q2 Overview
- FY2024 Forecast
- Topics



FY2024 Q2 Overview



Business environment

- The NHI drug price list revision in April 2024.
 - Decrease in drug prices
 (The drug price revision rate for all listed products was in the -9% range.)

■ Increase in import prices of active pharmaceutical ingredients and pharmaceutical formulations due to depreciation of the yen.

Summary of FY2024 Q2 (1/2)

Consolidated Financial Results

FY2024 Q2

Increase in Net sales Decrease in Operating profits Operating profits decreased due to the NHI Net sales increased due to the drug price revision and the increase in the cost growth of new drugs of sales ratio, which is caused by higher import prices of active pharmaceutical ingredients and pharmaceutical formulations due to (Billions of yen) depreciation of the yen. 49.4 51.0 3.9 (Billions of yen) 3.7

FY2023 Q2



FY2023 Q2

FY2024 Q2

Summary of FY2024 Q2 (2/2)

Progress in development pipeline

Ethical drugs

- Obtained manufacturing and marketing approval of Quviviq®, insomnia treatment
- Obtained approval for an additional indication of Treprost[®] Inhalation Solution for pulmonary hypertension associated with interstitial lung disease
- Filed a partial change application in approved matters of Lialda $_{\mathbb{R}}$ to add dosage and administration for pediatric patients
- Filed a new drug application for highly purified EPA drug (development code: MND-21) in China

Medical devices

Obtained 510(k) clearance for ReFeel® in the US

Business alliances

- Signed an agreement for the sale of Epadel in the ASEAN region and Taiwan
- Signed an agreement for the exclusive distribution of TYVASO DPI™



Consolidated operating results in FY2024 Q2

(Millions of yen)

	FY2023 Q2 (Y o Y changes)	FY2024 Q2 (Y o Y changes)	Y o Y value
Net sales	49,476 (▲ 7.0%)	51,096 (3.3%)	1,619
Operating profit	3,952 (▲25.1%)	3,793 (▲4.0%)	▲159
Ratio of operating profit to net sales	8.0%	7.4%	▲0.6 points
Ordinary profit	4,053 (▲ 25.5%)	4,079 (0.6%)	26
Profit attributable to owners of parent	2,838 (▲27.6%)	2,825 (▲0.5%)	▲13
Research and development expenses	4,855	4,776	▲79



Net sales by business in FY2024 Q2

(Millions of yen)

	FY2023 Q2 (Y o Y changes)	FY2024 Q2 (Y o Y changes)	Y o Y value
Net sales	49,476 (▲ 7.0%)	51,096 (3.3%)	1,619
Pharmaceuticals	46,286	47,555	1,269
business	(▲ 7.8%)	(2.7%)	
Healthcare	3,190	3,540	349
business	(6.4%)	(11.0%)	



Sales of major products in FY2024 Q2 (1/2)

(Billions of yen)

			FY2024 Q2		
Products		FY2023 Q2	Calac	Υo	Υ
			Sales -	Value	Ratio
New drugs					
Treatment of ulcerative co	litis Lialda _®	71	74	3	4%
Treatment for chronic constipation	Goofice®	37	41	3	8%
Treatment for chronic constipation	Movicol [®]	28	32	3	11%
Gout and hyperuricemia	Urece ®	15	21	5	35%
Treatment for pulmonary arte hypertension and pulmonary hypertension associated with interstitial lung disease	rial Treprost [®]	10	19	9	98%
Treatment of ulcerative co	litis Cortiment®*1	0	2	2	-
Treatment of ulcerative co	litis Omvoh [®] *2 (NHI price)	2	24	22	-

^{*1} Cortiment® was launched in September 2023.

^{*2} Omvoh® was launched in June 2023. Due to discussions with partners, sales of Omvoh® is shown in a NHI drug price basis.



Sales of major products in FY2024 Q2 (2/2)

(Billions of yen) FY2024 Q2 **Products** FY2023 Q2 YoY Sales Value Ratio Long-listed products **Drug for hyperlipidemia and Epadel** 38 29 **▲25%** arteriosclerosis obliterans Lexapro® **Antidepressant** ▲34% 26 **17** Calcium channel blocker with a Atelec® * 12 **▲26%** long-acting hypotensive effect Analgesic for chronic pain and pain Tramcet[®] **▲25%** 12 9 after tooth extraction Heparin **Anticoagulant agent** Sodium 6 0 3% 6 **MOCHIDA** Therapeutic agent for **▲21%** endometriosis, adenomyosis and Dinagest 5 4 **1** dvsmenorrhea 0 1% **150 151** Generic Drugs Therapeutic agent for Dienogest 5 13% endometriosis, adenomyosis and 49 43 dysmenorrhea

^{*}Sales of Atelec® are the sum of Atelec® and Atedio®.



Consolidated financial statements

(Millions of yen)

	FY2023	FY2024 Q2	YoY	Major fluctuation factors	(Millions of yen)
	(As of Mar. 31, 2024)	(As of Sep. 30, 2024)	value		Y o Y value
Total assets	158,800	158,434	▲365		
Total current assets	116,662	116,761	99	Cash and time deposits Accounts receivable Securities Other	7,401 ▲5,072 ▲1,501 ▲1,178
Total non- current assets	42,138	41,672	▲ 465	Property, plant and equipment Investments and other assets Deferred tax assets	127 ▲766 148
Total liabilities and net assets	158,800	158,434	▲365		
Total current liabilities	26,073	24,576	▲1,497	Notes and accounts payable Income taxes payable	▲ 2,342 815
Total non- current liabilities	4,759	4,751	▲7		
Total net assets	127,967	129,106	1,139	Dividends paid Profit attributable to owners of parent	▲1,418 2,825
	127,907	125,100		Unrealized gain on available-for-sal securities	≜ 229

Shareholder returns

Policy

- Maintaining a stable dividends while enhancing internal reserves for future business development
- Maintaining the dividend of at least 80 yen per share during the 22-24 MTP period

(Yen)

	FY2023	FY2024 (Forecast)
Annual dividends per	80.00	80.00
share	(interim 40.00)	(interim 40.00)



FY2024 Forecast



Prospects and Challenges for FY2024

Pharmaceuticals

- Focusing on targeted areas with a focus on new drugs
 - ✓ Expanding Lialda_®, Omvoh[®] and Cortiment[®] by focus on the gastroenterology
 - ✓ Further growth of Goofice[®] and Urece[®] etc.
 - **✓** Dinagest and Dienogest
- Changing business scheme of Quviviq® and terminating contracts related to sales.
- Promoting enhancement of development pipeline
- Focusing on new drug discovery modalities
 - ✓ Nucleic acids
 - **✓** Regenerative medicine products

Biomaterials

- Promoting each project based on alginate
 - ✓ Aiming to obtain approval for dMD-001
 - **✓** Expansion of ReFeel® in the US

Healthcare

Aiming for the continuous growth of the Collage Repair series and the Collage Furfur series



Consolidated financial result forecasts

(Millions of yen)

	FY2023 (Y o Y changes)	FY2024 Forecast (Y o Y changes)
Net sales	102,885 (▲0.4%)	106,000 (3.0%)
Operating profit	5,802 (▲31.8%)	7,500 (29.3%)
Ratio of operating profit to net sales	5.6%	7.1%
Ordinary profit	6,037 (▲33.5%)	7,700 (27.5%)
Profit attributable to owners of parent	4,547 (▲31.6%)	5,600 (23.1%)
Research and development expenses	12,554	13,200



Forecasts by business

(Millions of yen)

	FY2023 (Y o Y changes)	FY2024 (Y o Y changes)
Net sales	102,885 (▲0.4%)	106,000 (3.0%)
Pharmaceuticals	96,455	99,180
business	(▲0.9%)	(2.8%)
Healthcare	6,430	7,000
business	(8.6%)	(8.9%)



Forecasts of major products (1/2)

(Billions of yen)

		FY2024 Forecasts		asts
Products	FY2023	Color	ΥοΥ	
		Sales	Value	Ratio

New drugs

Treatment of ulcerative colitis	Lialda _®	145	146	1	1%
Treatment for chronic constipation	Goofice [®]	77	90	12	16%
Treatment for chronic constipation	Movicol [®]	59	60	0	1%
Gout and hyperuricemia	Urece ®	33	54	20	61%
Treatment for pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease	Treprost [®]	23	28	4	18%
Treatment of ulcerative colitis	Cortiment ^{® * 1}	2	14	12	619%
Treatment of ulcerative colitis	Omvoh [®] *2 (NHI price)	14	-	-	_

^{*1} Cortiment® was launched in September 2023.

^{*2} Omvoh® was launched in June 2023. Due to discussions with partners, Omvoh® forecast is not disclosed.



Forecasts of major products (2/2)

				(Billion	s of yen)
			FY2024 Forecasts		
Products Product Products Prod		FY2023	Sales -	Υo	Υ
			Sales	Value	Ratio
Long-listed products					
Drug for hyperlipidemia and arteriosclerosis obliterans	Epadel	74	65	▲8	▲12%
Antidepressant	Lexapro ®	52	37	▲15	▲29%
Calcium channel blocker with a long-acting hypotensive effect	Atelec®*	23	18	▲ 4	▲19%
Analgesic for chronic pain and pain after tooth extraction	Tramcet [®]	22	20	▲2	▲10%
Anticoagulant agent	Heparin Sodium MOCHIDA	13	12	▲0	▲5 %
Therapeutic agent for endometriosis, adenomyosis and dysmenorrhea	Dinagest	11	7	▲ 3	▲32%
Generic Drugs		326	285	▲41	▲13%
Therapeutic agent for endometriosis, adenomyosis and dysmenorrhea	Dienogest	92	92	0	0%

^{*}Sales of Atelec® are the sum of Atelec® and Atedio®.



Development Pipeline: Ethical drugs

			Stage			Remarks
Development code	Indications	Phase II	Phase III	Filed	Approved	<development country=""></development>
ACT-541468 *1	Insomnia					Co-development with Nxera Pharma Japan Co., Ltd. (Former Idorsia Pharmaceuticals Japan Ltd.) <japan></japan>
MD-711 *1	Pulmonary hypertension associated with interstitial lung disease (additional indication)					Licensed-in from United Therapeutics Corporation In-house development <japan></japan>
MD-0901*2	Ulcerative colitis (pediatric indication)					Licensed-in from Takeda Pharmaceuticals U.S.A., Inc. In-house development <japan></japan>
FYU-981	Gout and hyperuricemia (pediatric indication)					Co-development with FUJI YAKUHIN Co., Ltd. <japan></japan>
MND-21*2	Hypertriglyceridemia					Collaboration on development with Sumitomo Pharma (Suzhou) Co., Ltd. <china></china>
*1 Updates from August 2,	2024. *2 Updates from May 13, 20	24.				

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Development Pipeline: Medical devices

		Stage				
Development code	Intended use or indications	Therapeutic exploratory study	Therapeutic confirmatory study	Filed	Approved	Remarks <development country=""></development>
dMD-001	Articular cartilage lesion					In-house development <japan></japan>
dMD-002	Cavernous nerve injury					In-house development <japan></japan>
dMD-003	Post-operative adhesion					In-house development <japan></japan>

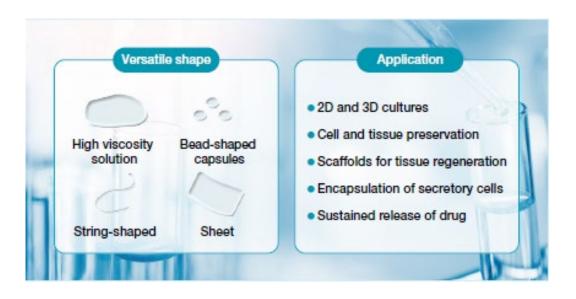


Topics



Biomaterials business

- Promoting and developing various projects in the biomaterials business based on alginate
 - ✓ A high polymeric substance derived from brown algae
 - **✓ Little impact on cells**
 - ✓ Possible to be processed into various forms and hardness





The cartilage repair material: dMD-001

 Composed of a sodium alginate solution with calcium chloride solution

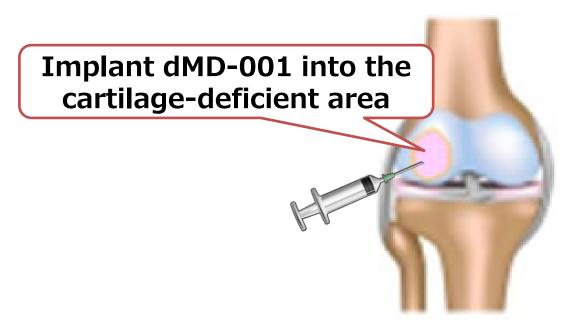


Sodium alginate solution



Calcium chloride solution





A material that supports nerve regeneration: ReFeel®

A sheet material composed of sodium alginate and polyglycolic acid nonwoven fabric

Product appearance of ReFeel®



Usage image

