

FY9/2021 Investor Meeting Materials

November 18, 2021

Fuji Pharma Co., Ltd.

TSE1

4554



FujiPharma

Chapter 1 FY9/21 Consolidated Financial Results

Chapter 2 FY9/22 Consolidated Forecast

Chapter 3 Mid-Term Business Plan Progress Summary

Chapter 4 Product Portfolio Developments



Chapter

1

FY9/21 Consolidated Financial Results

- **Net sales and profit increased year on year on consolidated and non-consolidated basis**
 - Net sales : Growth in women's healthcare products made up for the decline in diagnostic drugs
 - Expenses : YoY ▲2.8% due to decrease in sales commission and R&D expenses
 - OLIC: COVID-19 impacted CMO sales
- **R&D Related Topics**
 - FSN-011-01 : Approved in September 2021
 - FSN-013 : [Japan] Started Phase III in August 2021
[ASEAN] Applied for import license in Thailand in September 2021

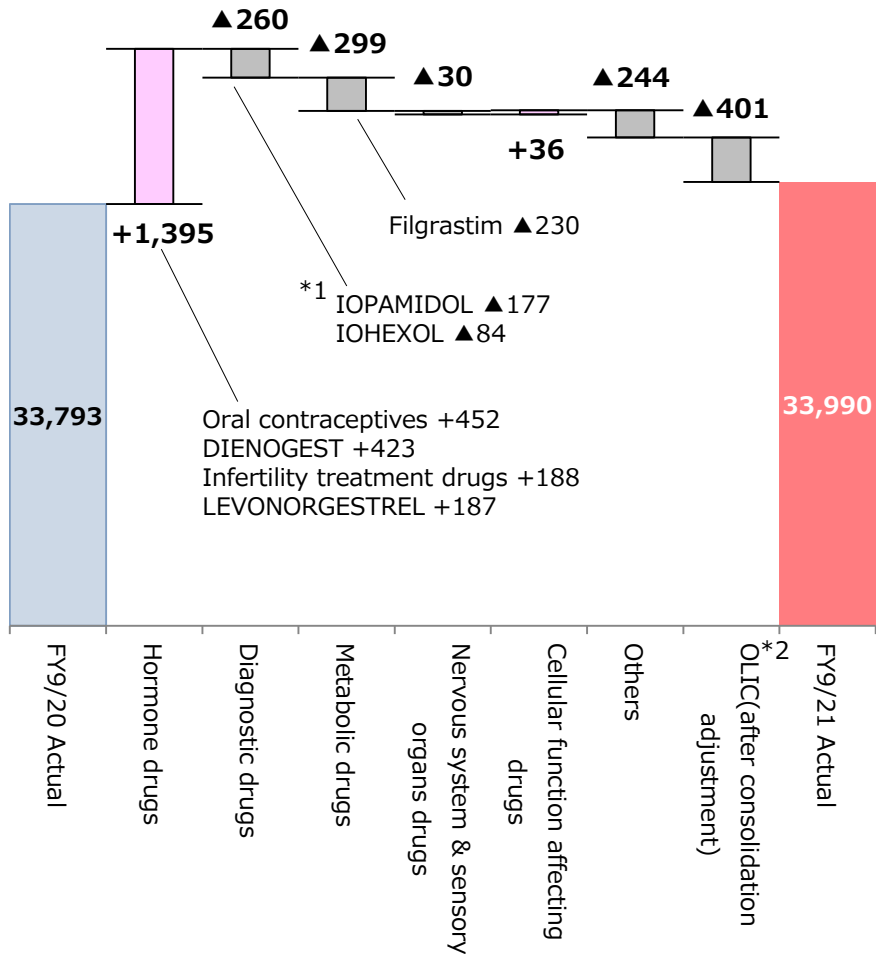
FY9/21 Consolidated Financial Results

- Net Sales : Increased by JPY 197 million (YoY+0.6%) - the increased sales of women's healthcare products covered the impact of NHI price revisions and COVID-19
- Operating Profit : Increased by JPY 210 million (YoY+6.7%) - Gross margin decreased due to the impact of NHI price revisions, offset by decrease in sales commission and R&D expenses

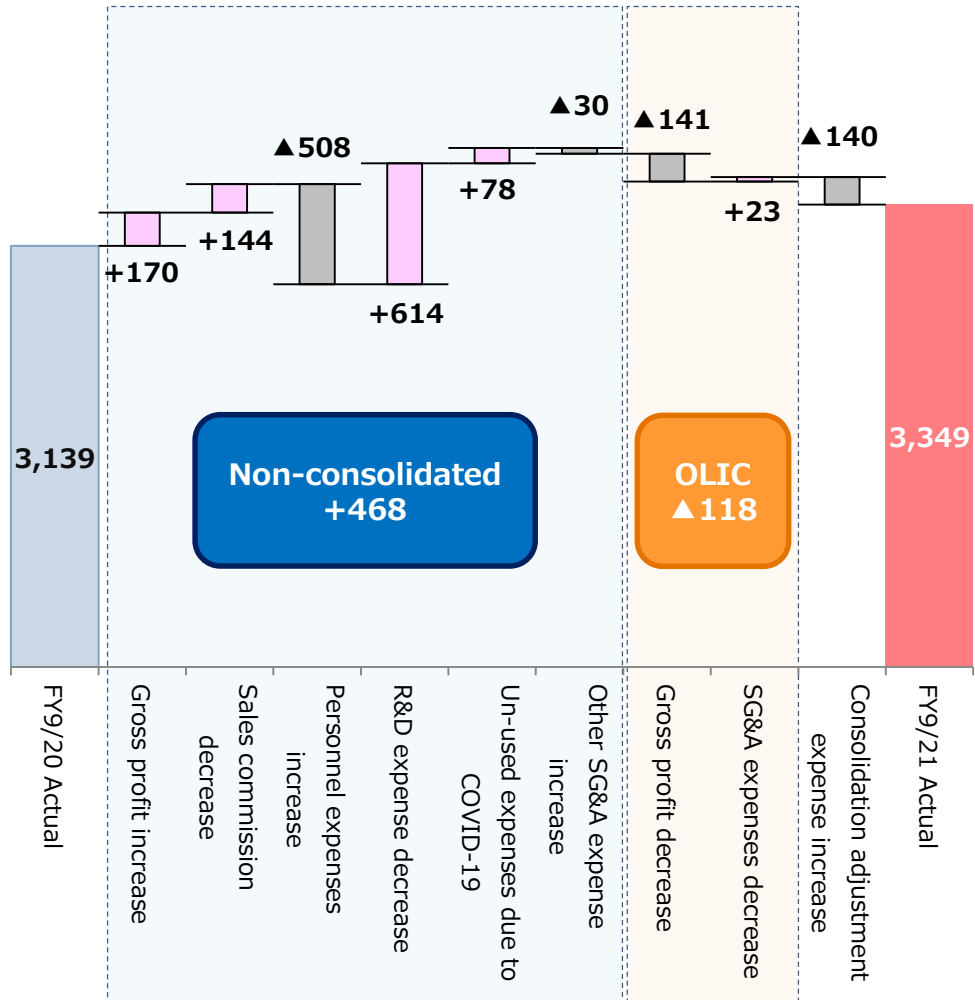
(¥million)	FY9/20	FY9/21	YoY Change		FY9/21	vs Fcst
	Full Year	Full Year	Amount	Ratio	Forecast	Amount
Net Sales	33,793	33,990	197	0.6%	34,702	▲ 712
Gross Profit	14,872	14,751	▲ 121	-0.8%	-	-
Gross Margin	44.0%	43.4%			-	-
SG&A Expenses	11,732	11,402	▲ 330	-2.8%	-	-
SG&A Margin	34.7%	33.5%			-	-
Operating Profit	3,139	3,349	210	6.7%	2,857	492
Operating Margin	9.3%	9.9%			8.2%	
Ordinary Profit	2,983	3,250	267	9.0%	2,807	443
Ordinary Margin	8.8%	9.6%			8.1%	
Profit Attributable to Owners of Parent	2,085	2,432	347	16.6%	2,100	332
Profit Margin	6.2%	7.2%			6.1%	
ROA	4.9%	5.2%				
ROE	5.3%	6.7%				
Net income per Share (Yen)	66.94	90.54				
Dividend payout ratio	43.3%	32.0%				
Capital Expenditure	2,965	3,392	427	14.4%	6,672	▲ 3,280
Depretiation (Including Leased Equipment)	1,858	1,893	35	1.9%	1,581	312
R&D Expenses	3,060	2,446	▲ 614	-20.1%	3,200	▲ 754
R&D Expenses Ratio	9.1%	7.2%			9.2%	

FY9/21 Consolidated Financial Results (YoY)

Net Sales (Unit:¥million)



Operating Profit (Unit:¥million)

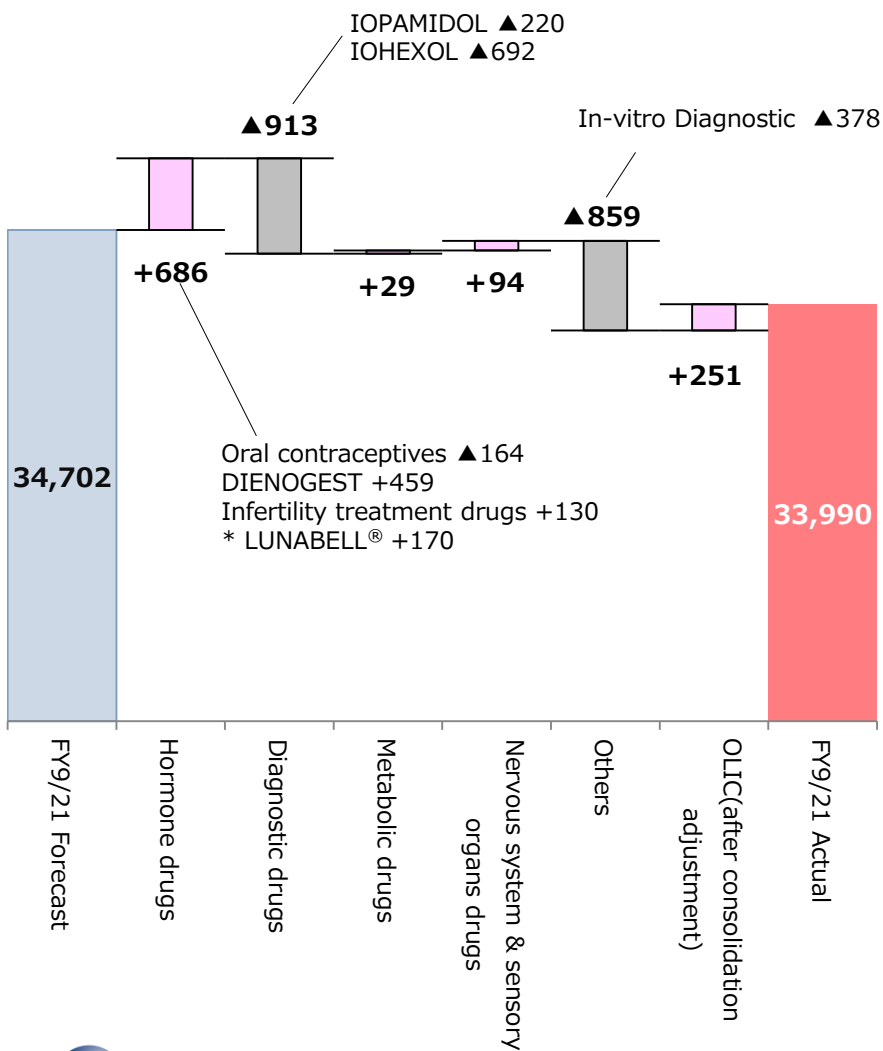


*1) Product name change : IOPAMIDOL injection (Former name : OYPALOMIN® injection) , IOHEXOL injection (Former name : IOPAQUE® injection)

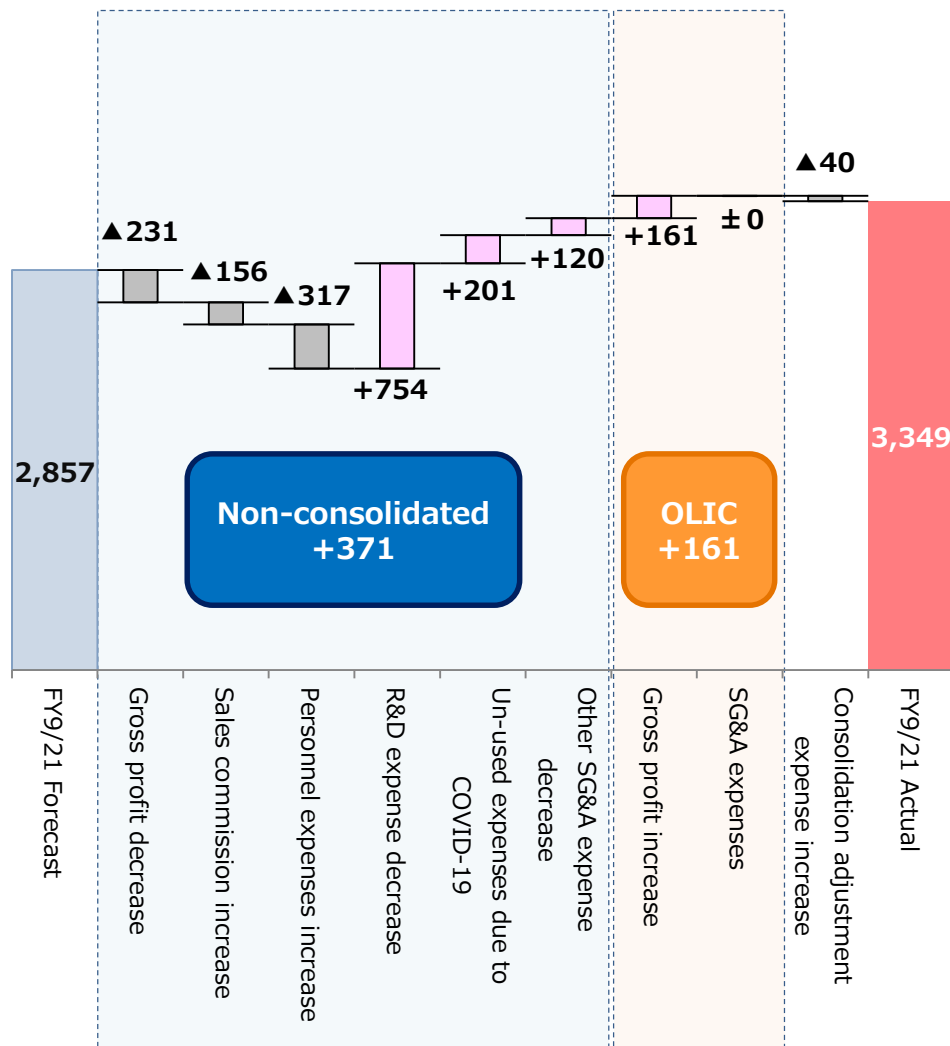
*2) OLIC : Our subsidiary CMO company (Head office and plant in Thailand)

FY9/21 Consolidated Financial Results (v. Forecast)

Net Sales (Unit:¥million)



Operating Profit (Unit:¥million)

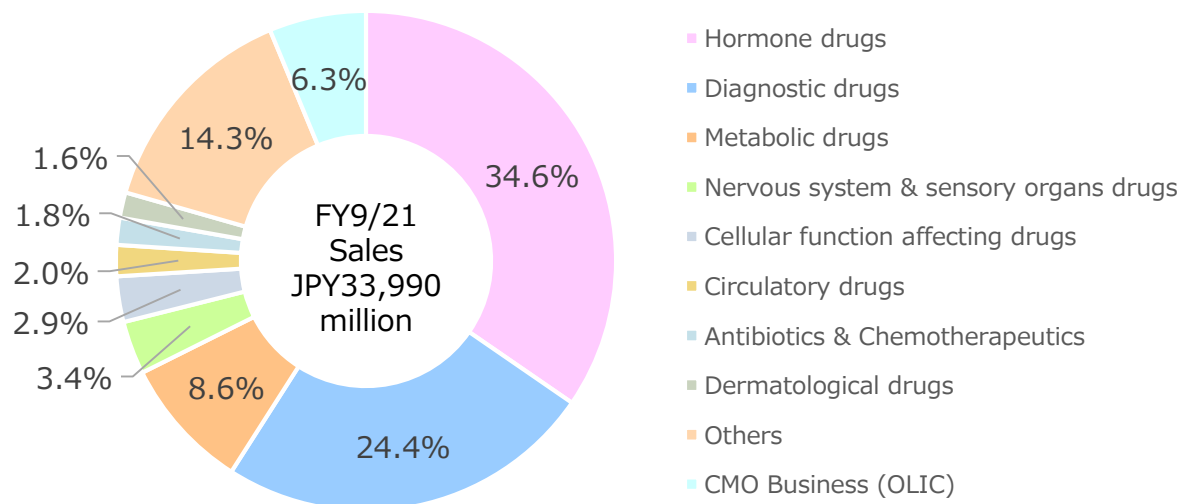


Sales by Therapeutic Category

(¥million)	FY9/17	FY9/18	FY9/19	FY9/20	FY9/21	YoY Change	
						Amount	Ratio
Hormone drugs	10,275	10,981	10,741	10,363	11,758	1,395	13.5%
Diagnostic drugs	13,473	14,323	10,827	8,570	8,310	▲ 260	-3.0%
Metabolic drugs	2,828	2,882	3,074	3,216	2,917	▲ 299	-9.3%
Nervous system & sensory organs drugs	197	165	1,099	1,200	1,170	▲ 30	-2.5%
Cellular function affecting drugs	627	881	932	966	1,002	36	3.7%
Circulatory drugs	945	925	891	714	683	▲ 31	-4.3%
Antibiotics & Chemotherapeutics	874	801	820	689	595	▲ 94	-13.6%
Dermatological drugs	384	505	537	538	558	20	3.7%
Others	3,380	3,966	4,815	5,000	4,862	▲ 138	-2.8%
<i>Of which, CMO Business (FUJI)</i>	953	1,471	2,303	2,798	3,146	348	12.4%
CMO Business (OLIC)	2,400	2,476	2,539	2,532	2,131	▲ 401	-15.8%
Total	35,387	37,909	36,279	33,793	33,990	197	0.6%

※CMO Business (OLIC) is the amount after consolidation adjustment

Sales Breakdown by Therapeutic Category



Sales of Major Products

Product Name (¥million)	Therapeutic Category	FY9/17	FY9/18	FY9/19	FY9/20	FY9/21	YoY Change		FY9/21 Budget
							Amount	Ratio	
★IOPAMIDOL injection	Diagnostic drugs	6,879	6,769	7,192	6,401	6,224	▲ 177	-2.8%	6,444
★IOHEXOL injection	Diagnostic drugs	2,162	2,010	2,287	2,172	2,088	▲ 84	-3.9%	2,780
Filgrastim BS Injection Syringe	Metabolic drugs	<u>1,671</u>	<u>1,721</u>	<u>1,974</u>	<u>2,299</u>	2,069	▲ 230	-10.0%	<u>2,099</u>
DIENOGEST tablets	Hormone drugs	307	828	1,136	1,311	1,734	423	32.2%	1,275
Favoir® tablets	Hormone drugs	601	552	768	1,019	1,331	312	30.6%	1,326
GABAPEN®	<u>Nervous system & sensory organs drugs</u>	-	-	-	<u>1,104</u>	1,092	▲ 12	-1.1%	1,009
Labellefile® tablets	Hormone drugs	398	526	709	862	1,002	140	16.2%	1,171
LUNABELL® tablets (LD/ULD)	<u>Hormone drugs</u>	<u>2,845</u>	<u>2,769</u>	<u>1,583</u>	<u>1,045</u>	978	▲ 67	-6.4%	<u>808</u>
DEXART® injection	Hormone drugs	866	870	894	874	961	87	9.9%	913
◆UTROGESTAN® vaginal capsules	Hormone drugs	<u>578</u>	<u>649</u>	<u>788</u>	<u>712</u>	889	177	24.8%	<u>859</u>
◆HMG intramuscular injection	Hormone drugs	891	880	811	752	883	131	17.3%	546
LEVONORGESTREL tablets	Hormone drugs	-	-	431	660	847	187	28.2%	864
LIMAPROST ALFADEX tablets	Metabolic drugs	572	621	591	498	488	▲ 10	-2.2%	433
◆BUSERELIN nasal solution	Hormone drugs	453	443	441	402	460	58	14.4%	422
◆Clomid®	<u>Hormone drugs</u>	<u>474</u>	<u>480</u>	<u>451</u>	<u>404</u>	422	18	4.2%	<u>461</u>
Total Top 15 Sales		18,704	19,124	20,064	20,524	21,472	948	4.6%	21,416
Pct. Of Total Sales		52.9%	50.4%	55.3%	60.7%	63.2%			61.7%
Other Products		14,282	16,308	13,675	10,736	10,386	▲ 350	-3.3%	11,405
CMO Business (OLIC)		2,400	2,476	2,539	2,532	2,131	▲ 401	-15.8%	1,879
Total		35,387	37,909	36,279	33,793	33,990	197	0.6%	34,702
[Reference]Branded contrast media		4,006	5,288	1,255	0	0			

Acute Medical Care Women's Healthcare

★Product name change : IOPAMIDOL injection (Former name : OYPALOMIN® injection) , IOHEXOL injection (Former name : IOPAQUE® injection)

◆Infertility Treatment drugs

* Underlined products are the Fuji Pharma branded drugs (branded drugs·branded generic drugs (transferred products) and biosimilars)

* CMO Business (OLIC) is the amount after consolidation adjustment

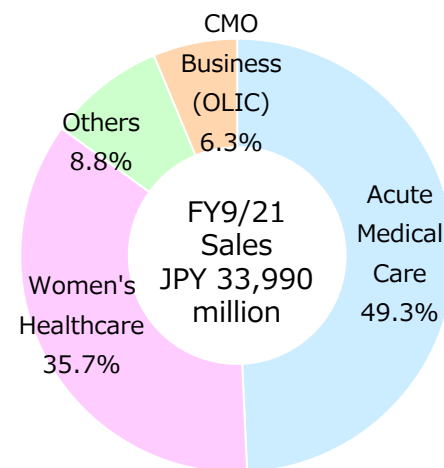


Sales by Medical Field and Dosage Form Category

Medical Field Category (¥million)	FY9/17	FY9/18	FY9/19	FY9/20	FY9/21	YoY	
						Amount	Ratio
Acute Medical Care	20,264	21,895	19,340	16,926	16,745	▲ 181	-1.1%
Women's Healthcare	10,212	10,802	10,756	10,836	12,138	1,302	12.0%
Others	2,509	2,734	3,643	3,497	2,975	▲ 522	-14.9%
CMO Business (OLIC)	2,400	2,476	2,539	2,532	2,131	▲ 401	-15.8%
Total	35,387	37,909	36,279	33,793	33,990	197	0.6%

※CMO Business (OLIC) is the amount after consolidation adjustment

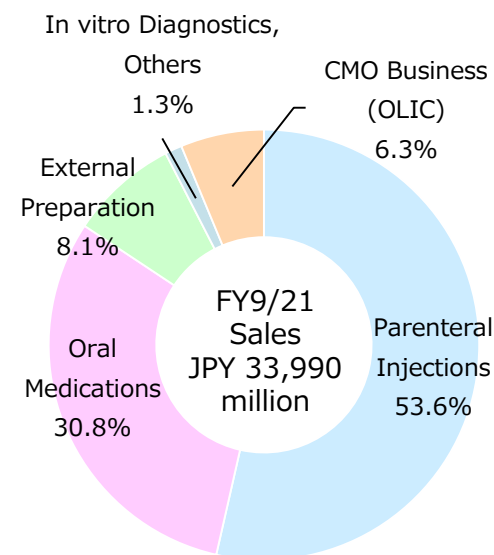
Sales Breakdown by Medical Field



Drug Form Category (¥million)	FY9/17	FY9/18	FY9/19	FY9/20	FY9/21	YoY	
						Amount	Ratio
Parenteral Injections	21,463	23,260	20,665	18,379	18,203	▲ 176	-1.0%
Oral Medications	8,547	8,937	9,729	9,799	10,456	657	6.7%
External Preparation	2,165	2,441	2,636	2,499	2,762	263	10.5%
In vitro Diagnostics, Others	811	793	709	581	436	▲ 145	-25.0%
CMO Business (OLIC)	2,400	2,476	2,539	2,532	2,131	▲ 401	-15.8%
Total	35,387	37,909	36,279	33,793	33,990	197	0.6%

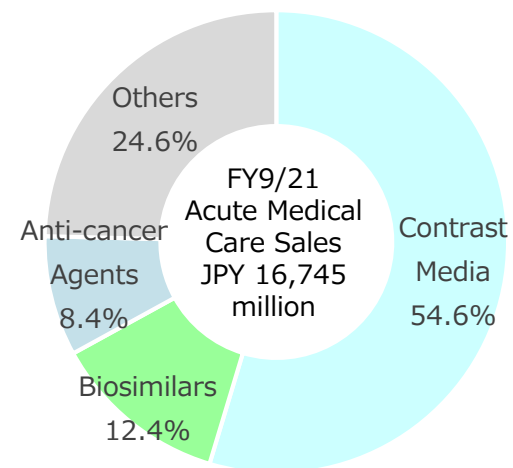
※CMO Business (OLIC) is the amount after consolidation adjustment

Sales Breakdown by Drug Form Category



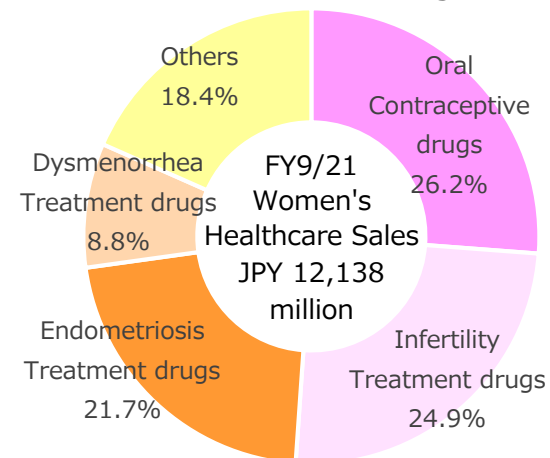
Sales of Acute Medical Care and Women's Healthcare

Acute Medical Care Net Sales Percentage



Acute Medical Care (¥Million)	FY9/17	FY9/18	FY9/19	FY9/20	FY9/21	YoY	
						Amount	Ratio
Contrast Media	13,193	14,062	11,852	9,423	9,151	▲ 272	-2.9%
Biosimilars	1,671	1,721	1,974	2,299	2,069	▲ 230	-10.0%
Anti-cancer Agents	862	1,166	988	1,095	1,404	309	28.2%
Others	4,537	4,945	4,524	4,107	4,119	12	0.3%
Total	20,264	21,895	19,340	16,926	16,745	▲ 181	-1.1%

Women's Healthcare Net Sales Percentage



Women's Healthcare (¥Million)	FY9/17	FY9/18	FY9/19	FY9/20	FY9/21	YoY	
						Amount	Ratio
Oral Contraceptive drugs	1,000	1,079	1,909	2,542	3,180	638	25.1%
Infertility Treatment drugs	2,865	3,021	3,100	2,848	3,022	174	6.1%
Endometriosis Treatment drugs	1,111	1,554	1,940	2,119	2,633	514	24.3%
Dysmenorrhea Treatment drugs	3,139	3,043	1,694	1,180	1,071	▲ 109	-9.2%
Others	2,095	2,103	2,110	2,145	2,230	85	4.0%
Total	10,212	10,802	10,756	10,836	12,138	1,302	12.0%

FY9/21 Summary of Consolidated Balance Sheet

(\$million)	FY9/20 Year End	FY9/21 Year End	YoY Change	
			Amount	Ratio
Assets				
Current Assets	34,975	34,834	▲ 141	-0.4%
Cash and Deposits	12,041	10,199	▲ 1,842	-15.3%
Notes and Accounts Receivable - Trade	11,700	11,866	166	1.4%
Inventories	10,682	12,007	1,325	12.4%
Other	549	761	212	38.6%
Non-current Assets	26,987	29,404	2,417	9.0%
Property, Plant and Equipment	12,767	14,392	1,625	12.7%
Intangible Assets	2,899	2,397	▲ 502	-17.3%
Investments and Other Assets	11,320	12,614	1,294	11.4%
Total Assets	61,962	64,239	2,277	3.7%
Liabilities				
Current Liabilities	11,004	20,192	9,188	83.5%
Notes and Accounts Payable - Trade	3,680	5,713	2,033	55.2%
Short-term Debt	1,000	7,000	6,000	600.0%
Current Portion of Long-term Debt	1,640	1,840	200	12.2%
Other	4,684	5,638	954	20.4%
Non-current Liabilities	10,996	11,365	369	3.4%
Long-term Debt	7,590	6,633	▲ 957	-12.6%
Other	3,406	4,732	1,326	38.9%
Total Liabilities	22,001	31,557	9,556	43.4%
Net Assets				
Share Capital	39,995	32,246	▲ 7,749	-19.4%
Capital Stock	3,799	3,799	0	0.0%
Capital Surplus	5,841	4,409	▲ 1,432	-24.5%
Retained Earnings	30,424	24,628	▲ 5,796	-19.1%
Treasury Shares	▲ 68	▲ 590	▲ 522	-
Accumulated Other Comprehensive Income	▲ 37	432	469	-
Total Net Assets	39,961	32,681	▲ 7,280	-18.2%
Total Liabilities and Net Assets	61,962	64,239	2,277	3.7%

Decrease due to Toyama plant CAPEX and share buy back

Increase in construction in progress and lease assets due to Toyama plant CAPEX

Borrowing for share buy back

Increase in lease obligations due to Toyama plant CAPEX

Decrease due to cancellation of treasury stock

FY9/21 Summary of Consolidated Statements of Cash Flows


(¥million)	FY9/20	FY9/21	YoY Change	
	Year End	Year End	Amount	Ratio
Cash Flows from Operating Activities	5,770	5,993	223	3.9%
(Major Breakdown)				
Profit before Income Taxes	2,918	3,371	453	15.5%
Depreciation	1,774	1,828	54	3.0%
Impairment Losses	-	11	-	-
Amortization of Goodwill	283	278	▲ 5	-1.8%
Increase (Decrease) in Provision for Bonuses	▲ 424	540	964	-227.4%
Decrease (Increase) in Trade Receivables	1,203	▲ 174	▲ 1,377	-114.5%
Decrease (Increase) in Inventories	▲ 23	▲ 1,340	▲ 1,317	5726.1%
Increase (Decrease) in Trade Payables	▲ 1,102	2,038	3,140	-284.9%
Income Taxes Paid	▲ 723	▲ 911	▲ 188	26.0%
Cash Flows from Investing Activities	▲ 2,616	▲ 2,345	271	-10.4%
(Major Breakdown)				
Proceeds from Sales of Investment Securities	-	189	-	-
Purchase of Property, Plant and Equipment	▲ 2,322	▲ 3,789	▲ 1,467	63.2%
Proceeds from Sales of Property, Plant and Equipment	26	1,673	1,647	6334.6%
Purchase of Intangible Assets	▲ 293	▲ 107	186	-63.5%
Cash Flows from Financing Activities	450	▲ 5,435	▲ 5,885	-1307.8%
(Major Breakdown)				
Net Increase (Decrease) in Short-term Loans Payable	1,000	6,000	5,000	500.0%
Proceeds from Long-term Loans Payable	4,000	1,000	▲ 3,000	-75.0%
Repayments of Long-term Loans Payable	▲ 3,140	▲ 1,756	1,384	-44.1%
Purchase of Treasury Shares	▲ 0	▲ 9,405	-	-
Cash Dividends Paid	▲ 904	▲ 807	97	-10.7%
Repayments of Lease Obligations	▲ 505	▲ 476	29	-5.7%
Cash and Cash Equivalents at Beginning of Period	8,494	12,041	3,547	41.8%
Cash and Cash Equivalents at End of Period	12,041	10,199	▲ 1,842	-15.3%
Free Cash Flows	3,154	3,648	494	15.7%

Sale of cross-shareholdings

Toyama plant CAPEX

Sale and lease back

Borrowing for CAPEX and share buy back



Chapter
2

FY9/22 Consolidated Forecast

- **Net sales and profits increase YoY 2 years in a row**

- Net sales : Increase of new products, new in-licensed products, existing women's healthcare products and OLIC
- Operating profit : Increase in sales contributes to profit increase despite increased R&D and other SG&A expenses
- Dividends : Plan to increase dividends for the first time in 3 years applying 30% payout ratio

- **R&D Related Topics**

- FSN-013 : [Japan] Continue Phase III
[ASEAN] Continue import license procedure
- Biosimilar : Apply for approval for 1 product

FY9/22 Consolidated Forecast

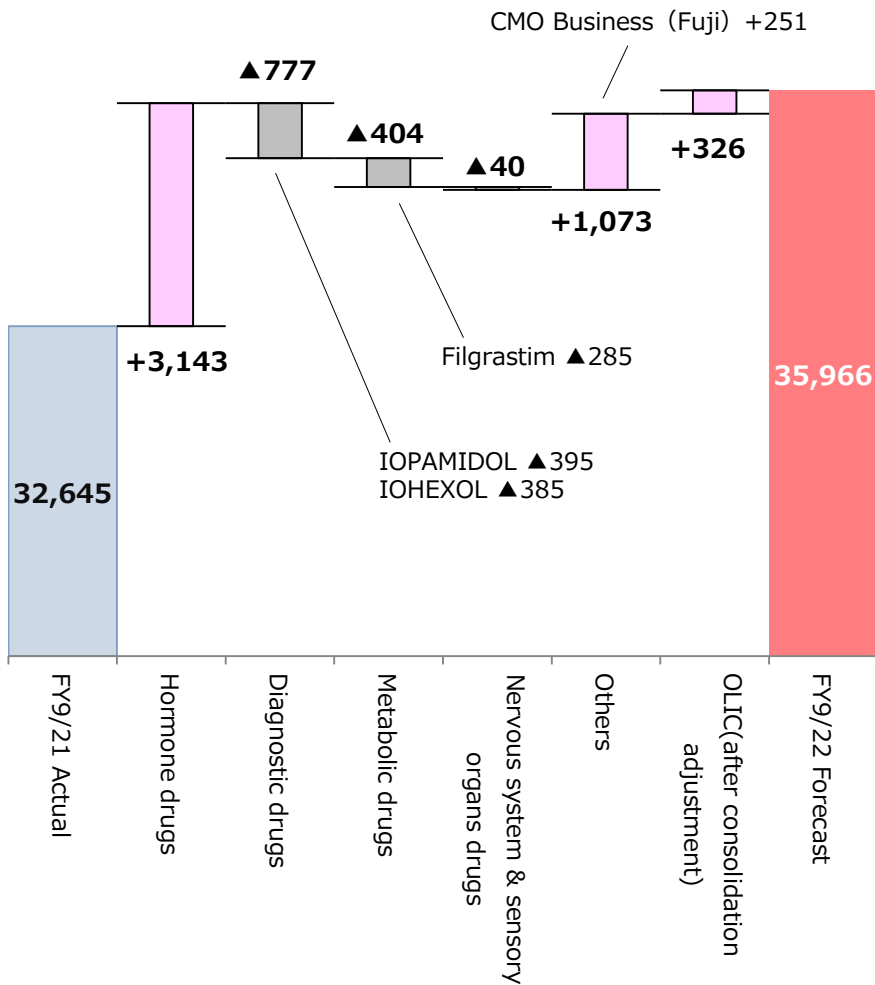
- Net sales : Increased by JPY 3,321 million (YoY+10.2%) - New products, new in-licensed products, existing women's healthcare products and OLIC offset impact of NHI price revisions and the decline in diagnostic drugs
- Operating profit : Increased by JPY 141 million (YoY+4.2%) - Increase in sales offsets increased depreciation, R&D, and other expenses

(¥million)	FY9/21 New accounting standards Actual	FY9/22 Forecast	YoY Change		reference
					FY9/21 Old accounting standards
			Amount	Ratio	Actual
Net Sales	32,645	35,966	3,321	10.2%	33,990
Operating Profit	3,349	3,490	141	4.2%	3,349
Operating Margin	10.3%	9.7%	-	-	9.9%
Ordinary Profit	3,250	3,540	290	8.9%	3,250
Ordinary Margin	10.0%	9.8%	-	-	9.6%
Profit Attributable to Owners of Parent	2,432	2,562	130	5.3%	2,432
Profit Margin	7.4%	7.1%	-	-	7.2%
Capital Expenditure	3,392	7,172	3,780	111.4%	3,392
Depreciation (Includind Leased Equipment)	1,893	1,760	▲ 133	-7.0%	1,893
R&D Expenses	2,446	2,809	363	14.8%	2,446
R&D Expenses Ratio	7.5%	7.8%	-	-	7.2%

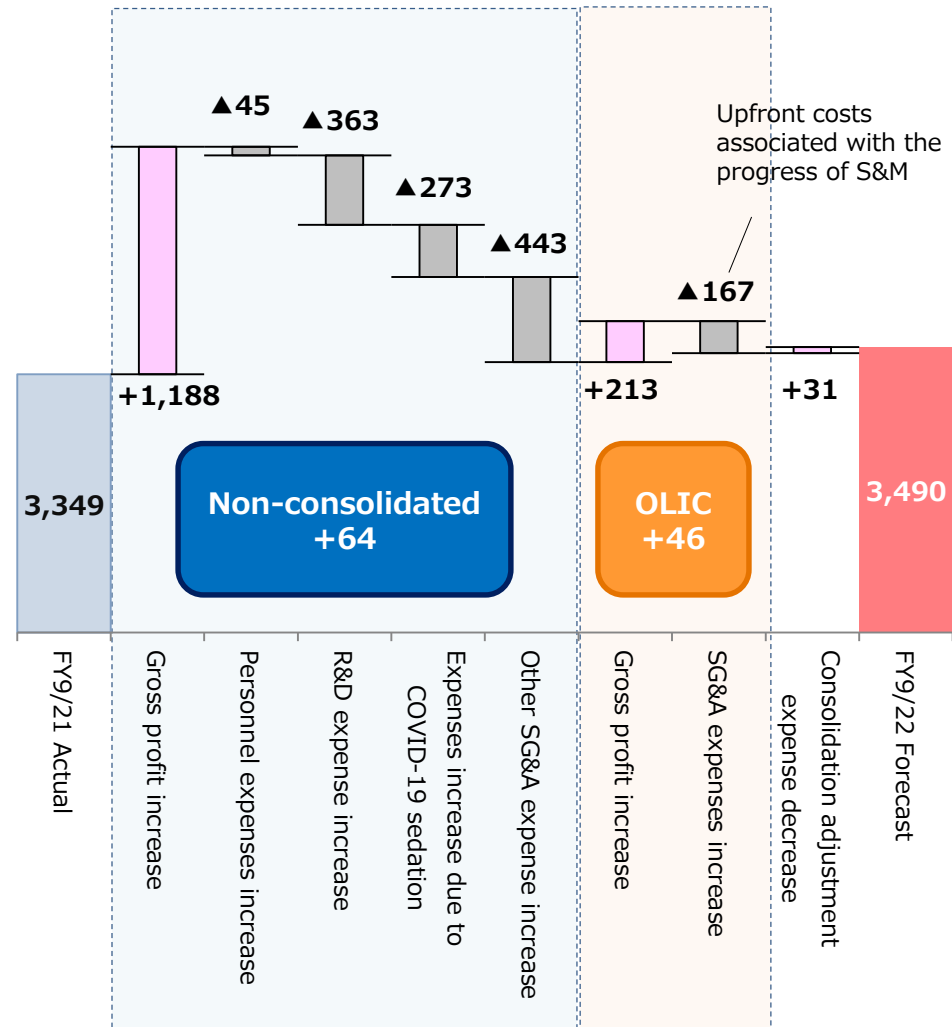
※ From the beginning of FY9/22, to apply "The Accounting Standards for Recognizing Revenues" (corporate accounting standard No. 29), the above-mentioned consolidated forecast is the amount after the application of new accounting standards. And YoY change (amount and ratio) is calculated on the assumption that new accounting standards were applied in FY9/21.

Summary of FY9/22 Consolidated Forecast (YoY)

Net Sales (Unit:¥million)



Operating Profit (Unit:¥million)



Sales Forecast by Therapeutic Category and Medical Field

(¥million)	FY9/21	FY9/22	YoY Change	
	Actual	Forecast	Amount	Ratio
Hormone drugs	11,758	14,901	3,143	26.7%
Diagnostic drugs	8,310	7,533	▲ 777	-9.4%
Metabolic drugs	2,917	2,513	▲ 404	-13.8%
Nervous system & sensory organs drugs	1,170	1,130	▲ 40	-3.4%
Cellular function affecting drugs	1,002	1,002	0	0.0%
Antibiotics & Chemotherapeutics	595	583	▲ 12	-2.0%
Circulatory drugs	683	524	▲ 159	-23.3%
Dermatological drugs	558	499	▲ 59	-10.6%
Others	3,517	4,819	1,302	37.0%
<i>Including CMO Business (FUJI)</i>	3,146	3,397	251	8.0%
CMO Business (OLIC)	2,131	2,457	326	15.3%
Total	32,645	35,966	3,321	10.2%

※CMO Business (OLIC) is the amount after consolidation adjustment

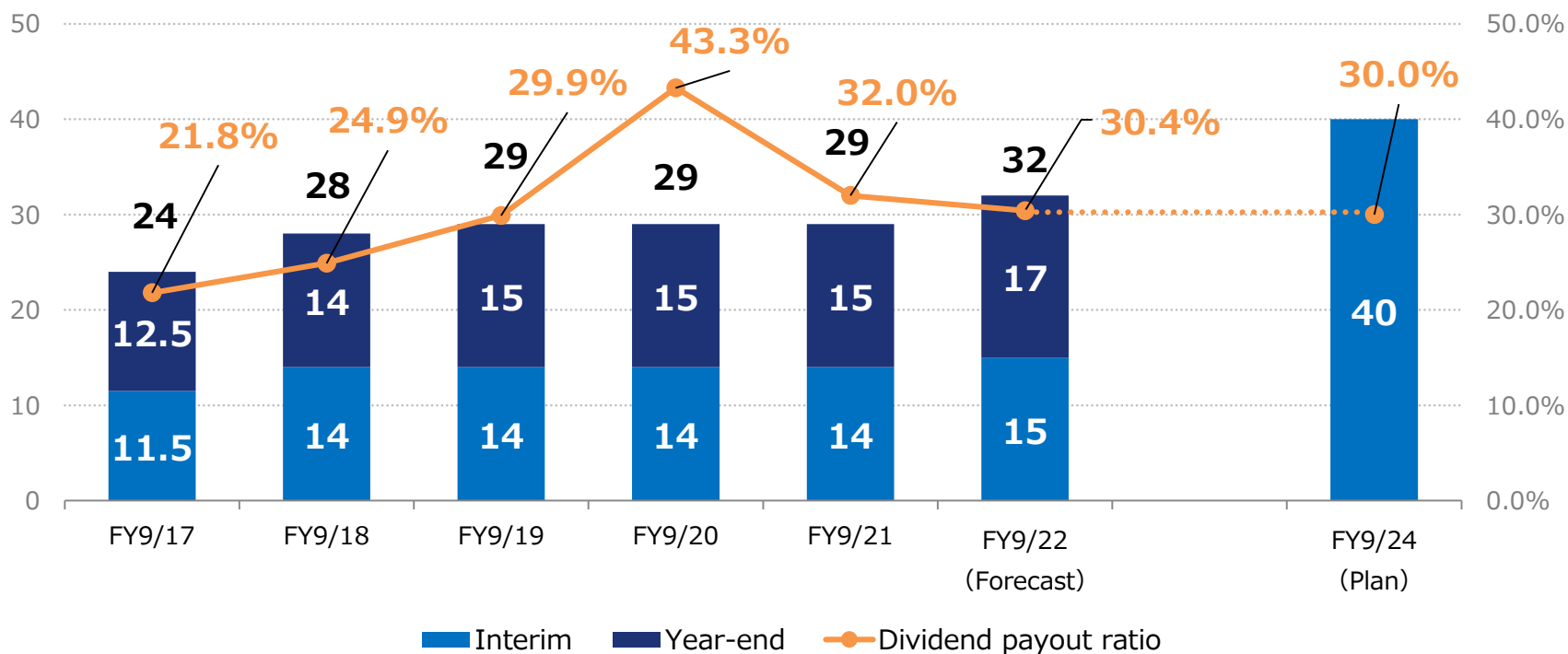
(¥million)	FY9/21	FY9/22	YoY	
	Actual	Forecast	Amount	Ratio
Acute Medical Care	16,745	15,643	▲ 1,102	-6.6%
Women's Healthcare	12,138	15,122	2,984	24.6%
Others	1,629	2,741	1,112	68.3%
CMO Business (OLIC)	2,131	2,457	326	15.3%
Total	32,645	35,966	3,321	10.2%

※CMO Business (OLIC) is the amount after consolidation adjustment

FY9/22 Shareholder Return Policy

- Our dividend policy is to achieve a dividend payout ratio of 30% with stable dividends.
- Therefore, we plan to pay 32 yen annual dividend by applying dividend payout ratio of 30% to FY9/22 forecast profit. (Interim 15 yen, Year-end 17 yen)

Dividend per share (JPY) / Dividend payout ratio (%)



※ On July 1, 2018, 1 common stock was split into 2 stock. Dividend per share assumes current total outstanding shares.

※ FY9/22 (Forecast) payout ratio is estimate at the beginning of fiscal year.

Chapter

3



Mid-Term Business Plan Progress Summary

Theme

Fujiらしくをあたらしく "Evolving Fuji"

Target in 9/2029

Goal

Business Plan based
on Vision for 2030

Positioning

Roadmap to achieve
Vision for 2030

Sales

JPY **100** bil+

Growth
Scenario

- No.1 in Women's Healthcare (WH)
- Evolving into sustainable Contrast Media business (CM)
- Establish Biosimilar business (BS)
- Strengthen overseas business (OS)

Operating Margin

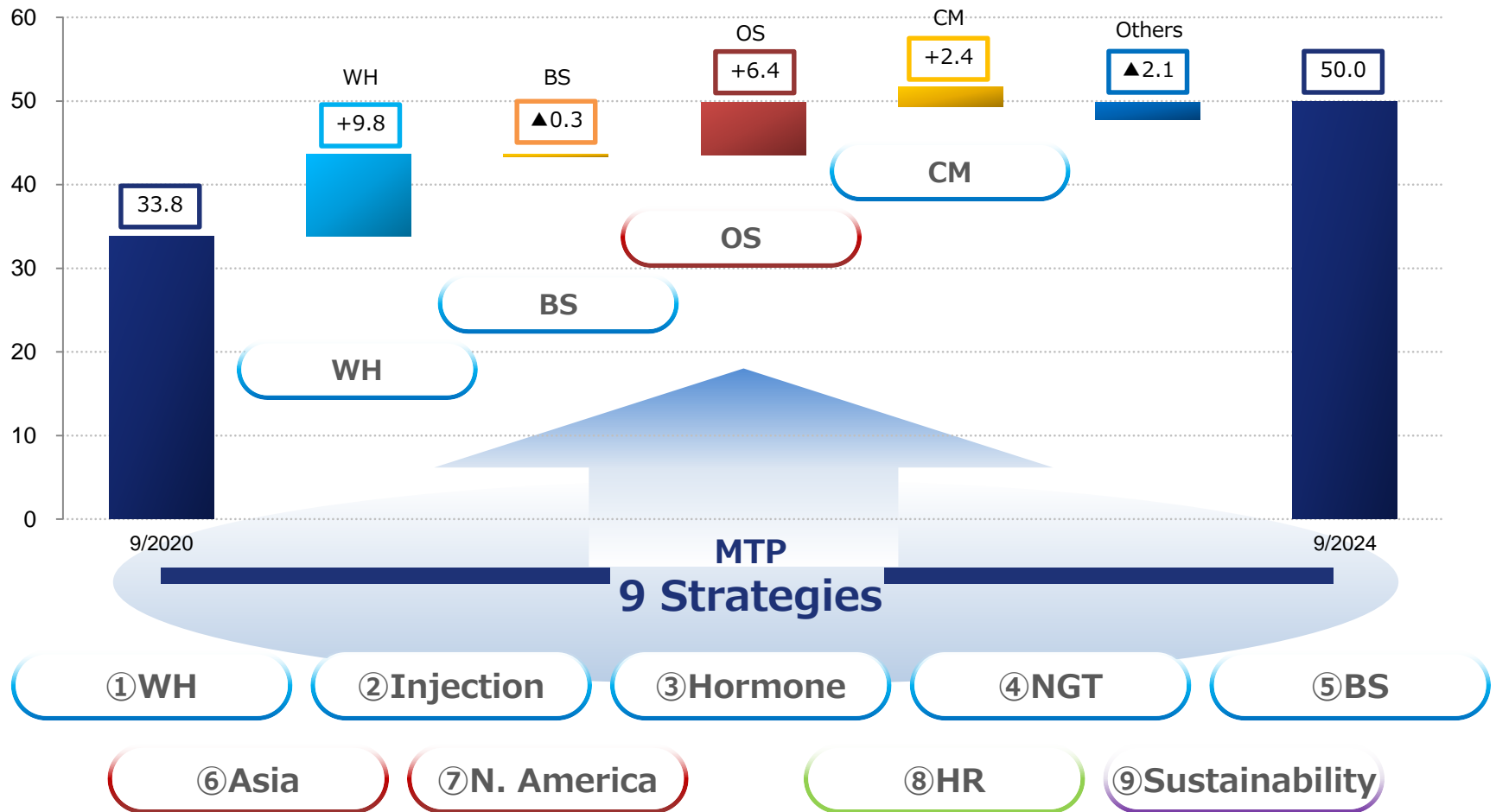
20%+

To Achieve

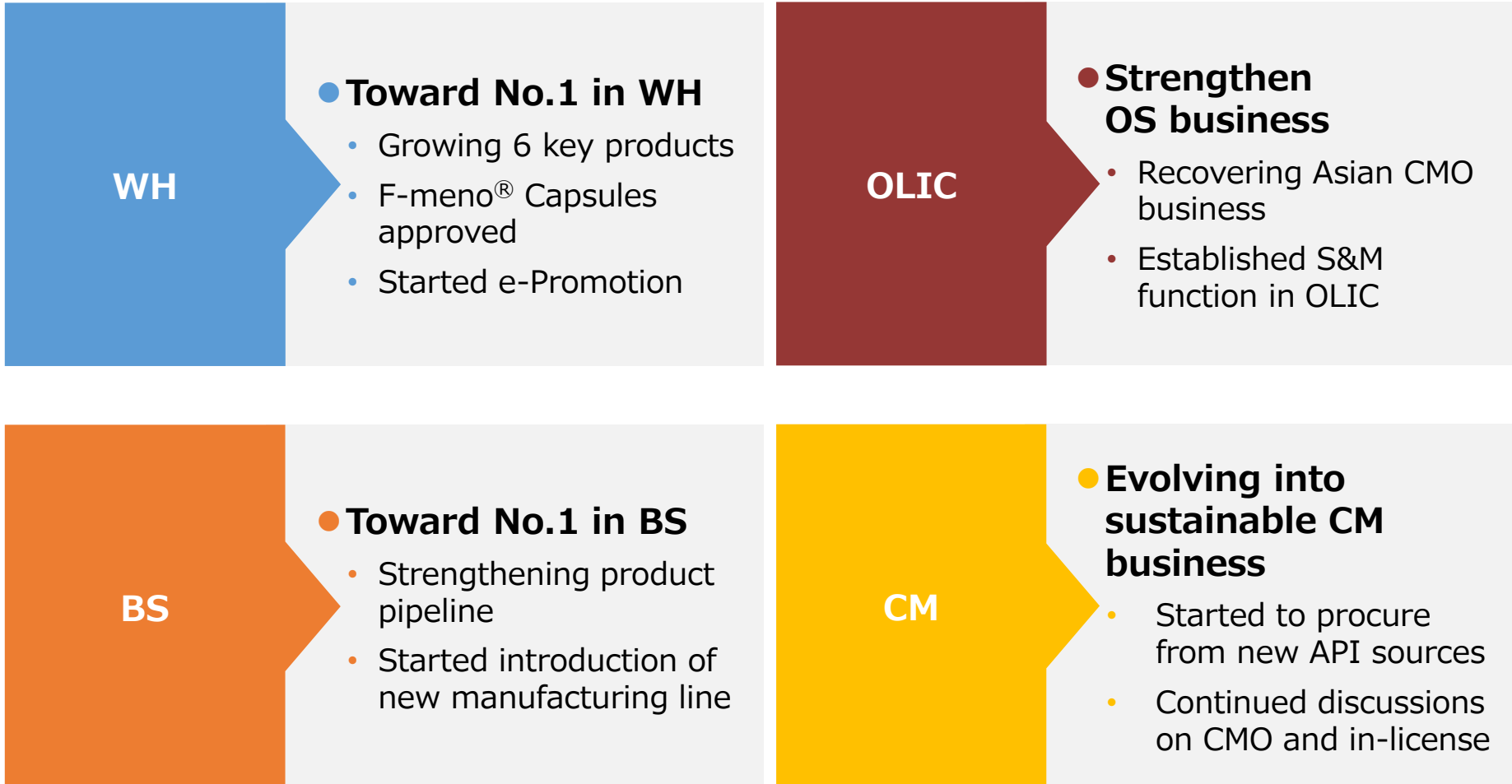
Execution through strategic and functional initiatives
Continuous monitoring review semi-annually
Rolled over every year

Financial Target (9/2024)

Sales (JPY bil)



Progressing toward “Net sales JPY 50 bil. for FY9/24”



FY9/21 Achievements

FY9/22 Actions

Increase Revenue of 6 Key Products

- Increased as planned (126% YoY, 105% vs. forecast)
- Steady progress in construction of new tablet building to meet strong demand

- Complete new tablet building (Start production in Nov. 2022)
- Promote oral contraceptive enlightenment activities
- Insurance coverage for infertility treatment (Scheduled for Apr. 2022)

Develop and Launch New Products

- F-meno[®] Capsules : Approved (Sep. 2021)
- FSN-013 : Started PhaseIII (Aug. 2021)

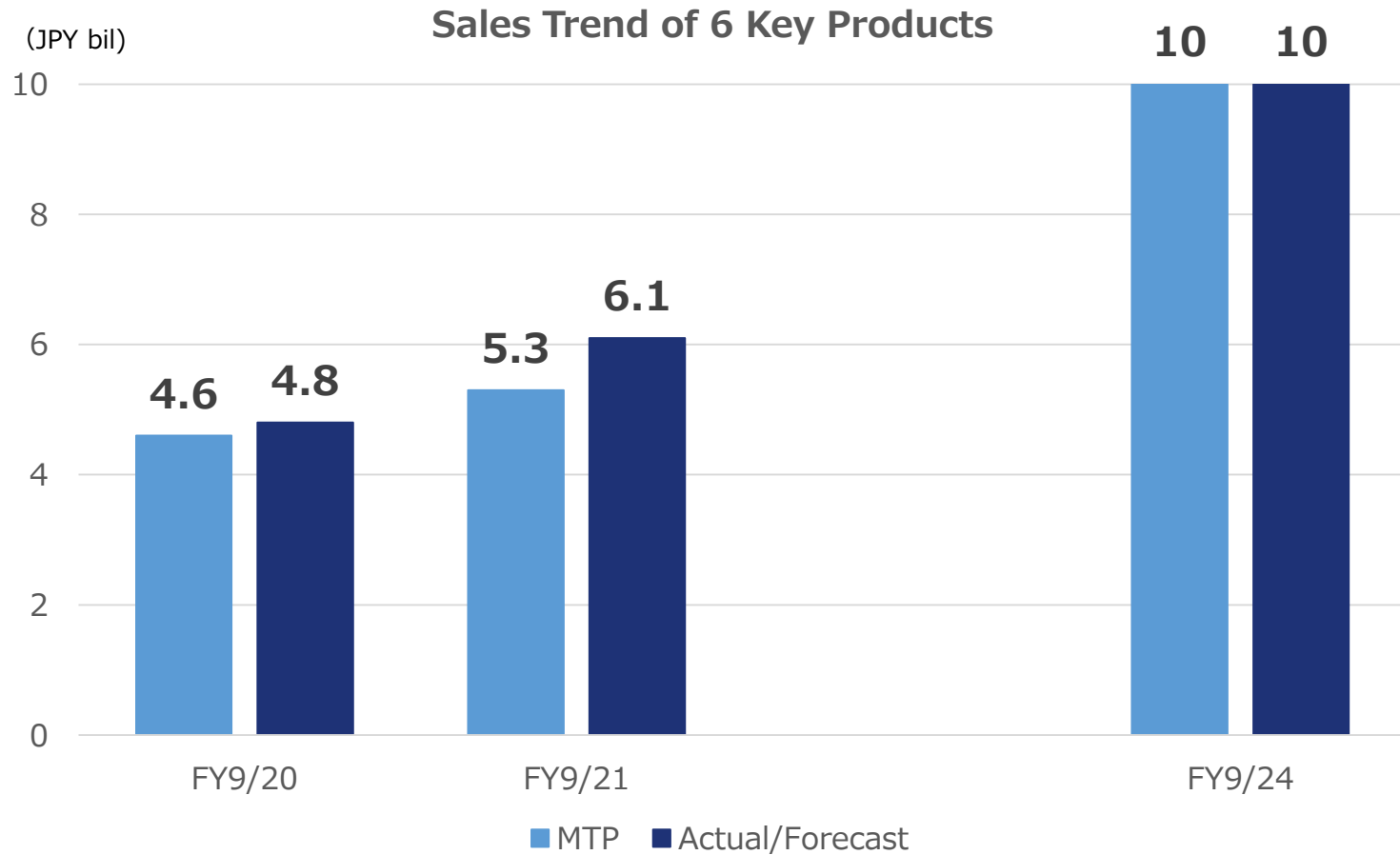
- 1 **F-meno[®] Capsules** : Launch
 - 2 **PROPESS[®]** : Start handling
 - 3 **FSN-013** :
Apply for approval in FY9/23
- Expand product pipeline

Increase Detailing by DX

- Signed co-promotion and development agreement with M3
- Started MR Productivity improvement system

- Start e-Promotion in F-meno[®] Capsules with M3
- Further utilize MR Productivity improvement system

Women's Healthcare ~6 Key Products



FY9/21 Achievements

FY9/22 Actions

Product Development

- Steady progress toward applying for approval of 1 Alvotech product in FY9/22
- Implemented Alvotech Product-development monitoring

- ⑤ Apply for approval of 1 Alvotech product
- ⑤ Prepare application of other Alvotech products

Strengthen Product Pipeline

- Development of other 4 Alvotech products progressed
- Continued negotiation of terms for 2 products with Alvotech

- Agree with Alvotech on 2 products
- Conduct a review on 1 product with different partner candidate

Acquire Manufacturing Capacity

- Started preparations for the introduction of high Potent multi-syringe line for product manufacturing

- Started the introduction of high Potent multi-syringe line (Aug. 2022)

FY9/21 Achievements

FY9/22 Actions

OLIC

- Mitigated COVID-19 impact by actively adding CMO contracts (104% vs. forecast)
- Steady progress to establish S&M function in OLIC, including application for approval of import license of FSN-013 in Thailand
- Effort to expand the portfolio (Development and product acquisition)
- Signed a CMO contract with the US company and introduced equipments




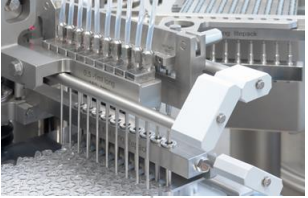


- Recover profits to levels prior to COVID-19
- ④ **FSN-013** : Seek approval of import license in Thailand (Target in 2022)
- ④ **FSN-013** : Sign a partner contract for ASEAN ex.Thailand
- Sign the contract to expand the portfolio
- Build the FSN-014 sales strategy
- Start the trial manufacturing and testing of CMO project for US

CM

- Based on the new API contracts, procurement started within this year (Reduction effect of about JPY 200 million / yr.)
- Continued detailed discussions on CMO and in-license

- Continued procurements based on new contract
- Improve operating rate through CMO, etc.
- Sign CMO contract

Capex on Toyama Plant

	2019	2020	2021	2022	2023
<p>New tablet building WH</p> <ul style="list-style-type: none"> ● Hormone tablet manufacturing / expand testing capacity ● High containment technology for hormone tablet manufacturing ● Response to PIC/S GMP inspection standards 		<p>Ground Breaking (Dec.)</p>	<p>-----></p>	<p>PV (Nov.)</p> 	
<p>Adding ampoule/vial line</p> <ul style="list-style-type: none"> ● Expand injection manufacturing capacity ● High containment technology for high pharmaceutical active injection formulation ● Response to PIC/S GMP inspection standards 		<p>Ground Breaking</p> 	<p>-----></p>	<p>PV (Nov.)</p> 	
<p>High Potent Multi-Syringe Line BS</p> <ul style="list-style-type: none"> ● Compatible with various syringe formulations and new products ● Expanding CMO business and exports to Europe and US ● Strengthen injection formulation technological Capabilities of Injection Formulations 				<p>Ground Breaking(Aug.) -></p> 	<p>PV (Oct.)</p>
<p>New packaging / warehouse building</p> <ul style="list-style-type: none"> ● Expand injection packaging capacity ● Expand product storage capacity ● Improve manufacturing workability 			<p>Ground Breaking(Jun.)</p>  <p>New warehouse building (plan)</p>	<p>-----></p> <p>Completion (Mar./Apr.)</p>  <p>New packaging building (plan)</p>	

Sustainability

- Sustainability Committee chaired by the president and Sustainability Section play a central role, positioning sustainability as one of 9 strategies of MTP, and pursue each of 7 core themes of ISO26000, to promote sustainability activities.
- Major Activities in FY9/21

Environment

- Built EHS system at Toyama Plant
Expect to get certification of ISO14001 and ISO45001 in Jan. 2022
- Started 3-year plan of Toyama Plant No.5 building LED replacement

Social

- Practiced enlightenment activities to solve health problems of women and offered excellent pharmaceuticals
- F-meno® Capsules approved**
- Improve female employee work environment
- Female manager ratio 21%**
Female director/auditor 3
- Disclosed quality control system
 - Supported the Seiichi Imai Memorial Foundation

Governance

- Continuous improvement of the governance system through response to the Corporate Governance Code, evaluation of the effectiveness of the Board of Directors, etc.
- Promote diversity and effectiveness of the board

Outside directors 60%
Independent directors 50%
Disclose skill map

Quality Control Initiatives

- **Launched web page on quality initiatives in July 2021.**

<https://www.fujipharma.jp/company/quality/>

- ▣ Quality policy

- 1.Thoroughly comply with laws and regulations
- 2.Guarantees high quality and reliability
- 3.Pursuing the latest manufacturing technologies
- 4.Focus on improving the quality of pharmaceuticals
- 5.Develop Human Resources

- ▣ Disclosure of the inspection plan and progress of the manufacturing and marketing approval

- Progress (as of the end of Oct. 2021)

Inspection of each manufacturing site	63.6%
Inspection by the manufacturer and distributor	51.3%


- ▣ Disclosed responsible officers and 3 responsible persons as a MA holder

- Responsible officer

Chairman and Representative Director	Hirofumi Imai
President & CEO, General Manager of Research & Development Division	Takayuki Iwai
Director	Takayuki Kasai
Director, Vice President, General Manager of Toyama Plant	Toyoyuki Kamide

- 3 responsible persons

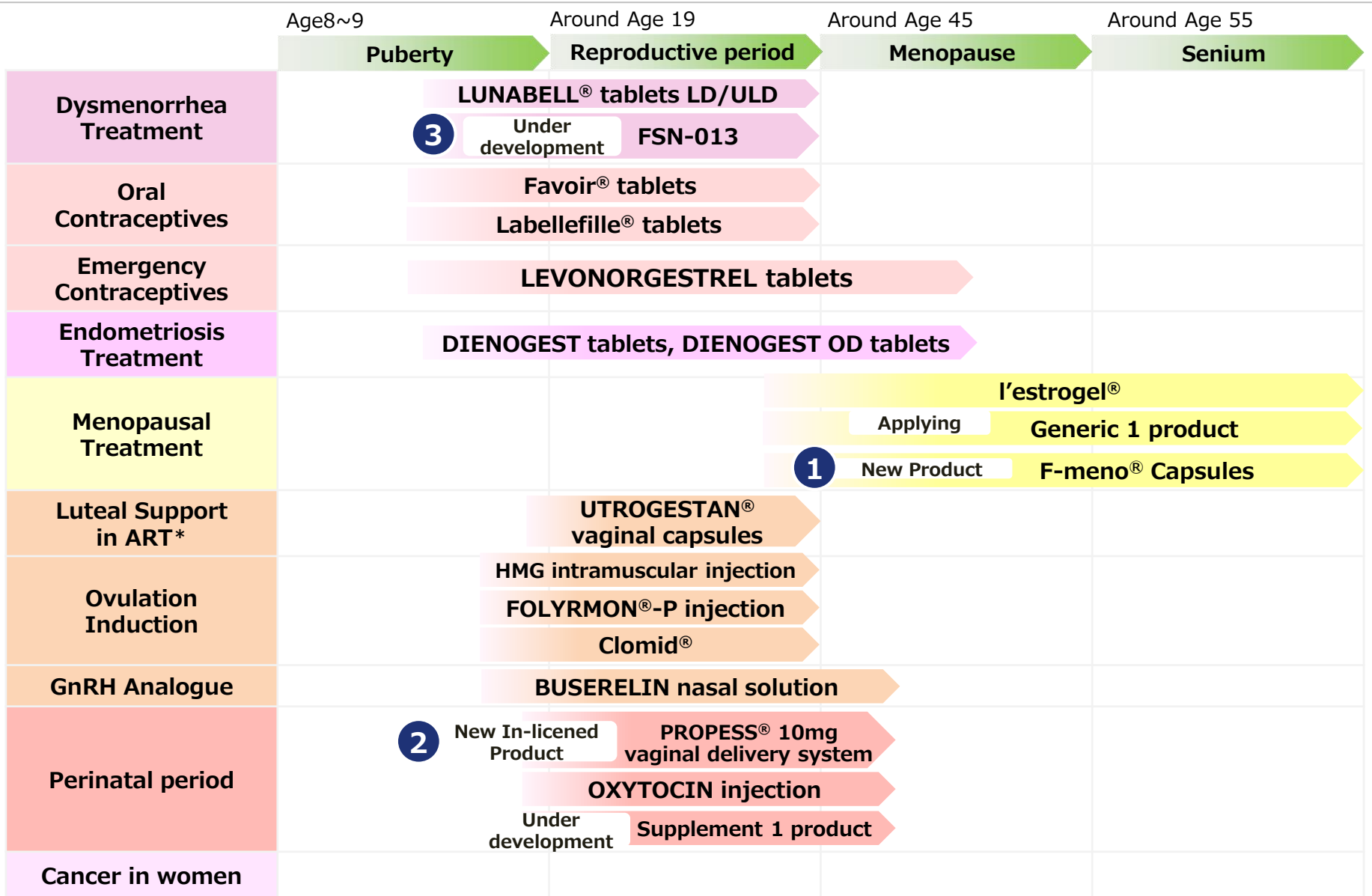
Chief Pharmaceutical Officer	Satomi Sawada (pharmacist) Corporate Officer, General Manager of Regulatory Compliance Department
Quality Assurance Manager	Mitsuo Mizuguchi Manager of Quality Assurance Group, Regulatory Compliance Department
Safety Control Manager	Nao Takigawa (pharmacist) Leader of Drug Safety Management Third Section, Regulatory Compliance Department



Chapter
4

Product Portfolio Developments

WH ~Our Strengths



* ART = Assisted Reproductive Technology



1 WH ~F-meno[®] Capsules

Brand name : **F-meno[®] Capsules 100mg (approved in Sep. 2021)**

Indications : Prevention of endometrial hyperplasia upon administration of estrogen drug for menopausal disorders and ovarian deficiency symptoms

History

- In Japan, there has been no progestogen drug indicated for hormone replacement therapy.
- Products for which development requests have been received from the Japan Society of Obstetrics and Gynecology and the Japan Society for Menopause and Women's Health for use in hormone replacement therapy, and for which development requests have been approved as having high medical necessity by the Review Committee on Unapproved or Off-label Drugs with High Medical Needs.

Features

- This is the first progestin drug to be approved for menopause-related indications in Japan, and obstetricians and gynecologists have commented that they hope the introduction of this product will promote the spread of hormone replacement therapy and improve the QOL of menopausal women.
- The only oral natural progestogen drug available in Japan.
- Products for which prevention of endometrial hyperplasia has been confirmed by domestic and overseas studies (to prevent the risk of uterine cancer due to endometrial proliferation).
- Overseas guidelines suggest that the risk of breast cancer is not different from that of non-users.
- No adverse effect on lipid^{※1} metabolism compared to synthetic progestogen.

※1) Lipids include triglycerides and cholesterol. Dyslipidemia refers to a condition in which lipid metabolism is abnormal and blood levels are outside the normal range. Dyslipidemia is a major risk factor for atherosclerosis, and if left untreated, it can lead to atherosclerotic diseases such as cerebral infarction and myocardial infarction.

Based on the results of an Internet survey of 3,888 women in the menopausal age group (40-60 years old) ^{※2}, it is estimated that more than half of all menopausal women, or about 7 million people, have menopausal symptoms.

※2) Survey report on menopausal disorders and their symptoms : QLife

2 WH ~PROPESS® 10mg vaginal delivery system

Strategic collaboration with Ferring Pharmaceuticals about PROPESS® in Japan
From Dec. 1, 2021, Fuji Pharma will be responsible for the sales and distribution
→Expanding product portfolio in women's healthcare in perinatal area

Outline

Brand Name: PROPESS® 10mg vaginal delivery system

Generic Name: Dinoprostone

Approval date: January ,2020

Launch date: April ,2020

Indications: Initiation of cervical ripening for patients from 37 completed weeks of gestation

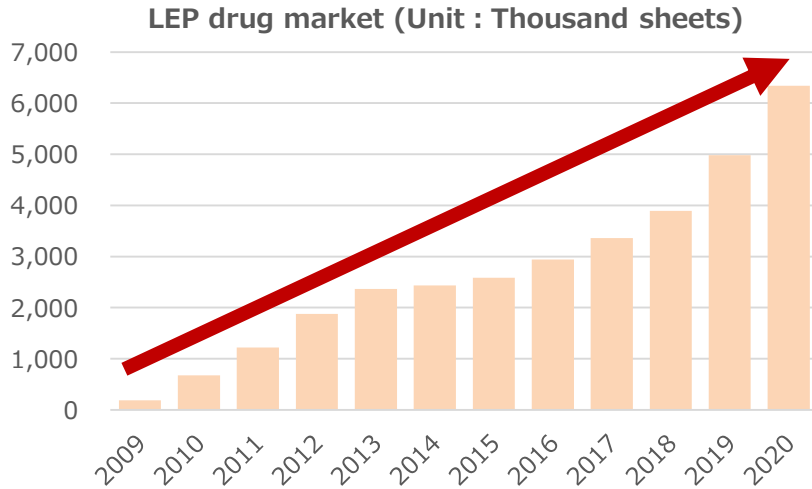
Features

- Product indicated for cervical ripening. (Prostaglandin E₂ formulation)
- Only vaginal product for initiation of cervical ripening for patients from 37 completed weeks of gestation
- Not listed in the NHI drug price standard
- Outside Japan, vaginal administration of prostaglandin E₂ is the standard method for promoting cervical ripening.
- Product has been approved in more than 70 countries or regions as a drug for initiation of cervical ripening (as of Dec. 2020)
- In Japan, Ferring conducted clinical trials and received manufacturing and marketing approval in Jan. 2020

Positioning of FSN-013 : New stage for Fuji as a market leader in Dysmenorrhea

LUNABELL® tablets

- Launched in July 2008
- Approved as the first in Japan product with dysmenorrhea indication
- Formed and expanded the market by contributing to patients suffering from dysmenorrhea



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Source: In-house totals based on IQVIA data JPM (September 2009-September 2020 MAT)
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FSN-013

- **Next generation drug for dysmenorrhea**
- It is expected to reduce the side effects reported with conventional drugs for dysmenorrhea.

Provides new treatment option

Started Phase III (Aug. 2021)

Overview

- Next-generation novel dysmenorrhea drugs
- Combination with progesterone (drospirenone)
- Estetrol is a novel unique estrogen
- It is expected and developed to reduce the commonly reported side effects of a combination containing estrogen (ethinylestradiol), which is used in conventional LEP.
- Approved in US and Europe

Characteristics

- Lower coagulant impact compared with existing products
- Lower interaction among drugs
- Expect better bleeding control
- Lower lipid impact
- Less likely to gain weight

Development in Japan

- Indication :** Dysmenorrhea
Improvement effect on pain associated with endometriosis
- Stage :** Conducting Phase III
- Launch :** 2024 (target)

3 WH ~FSN-013 : Outline of Japan Phase III (Study No. FSN-013-03)

Test Purpose	A total of 28 days of administration of FSN-013(Estetrol [E4] 15 mg/drospirenone [DRSP] 3 mg combination tablet) for 24 days followed by placebo tablets for 4 days in Japanese patients with dysmenorrhea are taken as one cycle. To test the superiority of four cycles (16 weeks) of FSN-013 over placebo for its efficacy in dysmenorrhea. In addition, the long-term safety of administration of 13 cycles (52 weeks) will be examined.
Design	Multicenter, randomized, double-blind, placebo-controlled, parallel group
Number of cases	150 cases (75 cases in FSN-013 group and 75 cases in the placebo group)
Subject	Patients with dysmenorrhea
Dosage and administration	<p>① The test drug (E4 15 mg/DRSP 3 mg combination tablets) will be administered for 24 days, followed immediately by a placebo tablet for 4 days. A total of 28 days is set as 1 cycle, and a total of 13 cycles of 4 cycles (comparative test phase) and 9 cycles (continuous treatment phase) are administered.</p> <p>② The administration of placebo tablets for 28 days is set as one cycle. Then, this administration is performed for 4 cycles (comparative test phase). Subsequently, the test drug will be administered for 24 days, followed immediately by a total of 28 days of placebo tablets for 4 days are taken as one cycle. Then, this administration is performed for 9 cycles(continuation phase). A total of 13 cycles of administration.</p>
Evaluation items	<p>Primary endpoint : The amount of change in the total score for dysmenorrhea from the baseline run-in period to the controlled study period (4 cycles, 16 weeks)</p> <p>Secondary endpoint : Evaluation scale of pain for dysmenorrhea (VAS) Change from baseline observation phase, etc.</p> <p>Safety endpoint : Incidence of adverse events and adverse drug reactions</p>

3 WH ~FSN-013 : Outline of Japan Phase III (Study No. FSN-013-04)

Test Purpose	A total of 28 days of administration of FSN-013(Estetrol [E4] 15 mg/drospirenone [DRSP] 3 mg combination tablet) for 24 days followed by placebo tablets for 4 days in Japanese patients with endometriosis are taken as one cycle. To test the superiority of four cycles (16 weeks) of FSN-013 over placebo for its efficacy in terms of changes in pelvic pain (lower abdominal pain/lower back pain). In addition, the long-term safety of administration of 13 cycles (52 weeks) will be examined.
Design	Multicenter, randomized, double-blind, placebo-controlled, parallel group
Number of cases	150 cases (75 cases in FSN-013 group and 75 cases in the placebo group)
Subject	Patients with endometriosis
Dosage and administration	<p>① The test drug (E4 15 mg/DRSP 3 mg Combination Tablets) will be administered for 24 days, followed immediately by a placebo-tablet for 4 days. A total of 28 days is set as 1 cycle, and a total of 13 cycles of 6 cycles (comparative test phase) and 7 cycles (continuous treatment phase) are administered.</p> <p>② The administration of placebo tablets for 28 days is set as one cycle. Then, this administration is performed for 6 cycles (comparative test phase). Subsequently, the test drug will be administered for 24 days, followed immediately by a total of 28 days of placebo tablets for 4 days are taken as one cycle. Then, this administration is performed for 7 cycles(continuation phase). A total of 13 cycles of administration.</p>
Evaluation items	<p>Primary endpoint: VAS change in most severe pelvic pain (lower abdominal and lower back pain) from the baseline observation period to the comparative study period (week 24).</p> <p>Secondary endpoints: Pelvic pain (lower abdominal and lower back pain) during menstrual or withdrawal bleeding, etc.</p> <p>Safety endpoints: Incidence of adverse events and adverse drug reactions</p>



Thailand

- September 2021 : Applied for import license of FSN-013 in Thailand (Accepted in November 2021)
- Sale & market by OLIC
- Approval procedure is proceeding as planned



ASEAN ex. Thailand

- Sublicense to partners
- Several countries including Philippines are under discussion with multiple partner candidates
- Country with higher market potential is prioritized

ASEAN

- Indications :** Contraception
- Stage :** Applied for import license of FSN-013 in Thailand
Approved in the US and Europe

Overseas (Phase III)

Trial : Open trial

Target : Healthy female adults

Term : 52 cycles

Dosage & administration:

1 cycle (28 days), once a day, 1 tablet orally for 24 consecutive days followed by placebo for 4 consecutive days

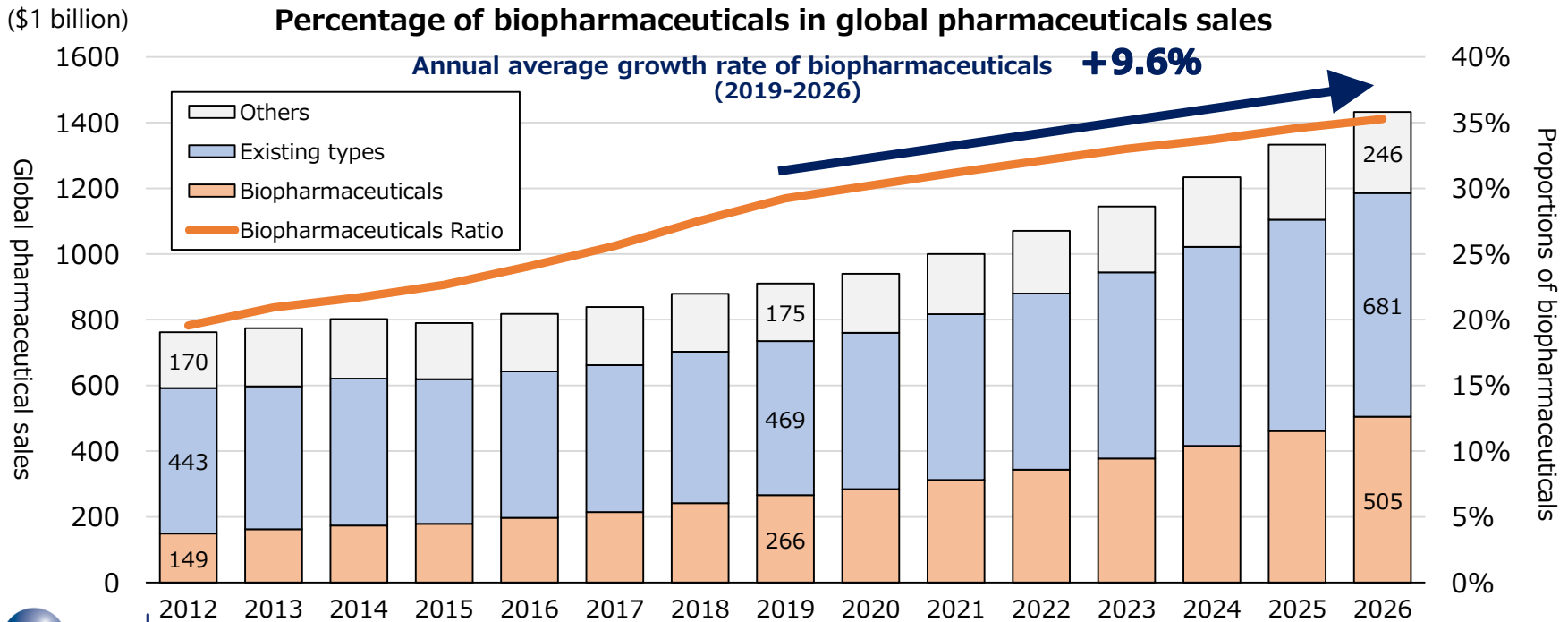
Results : Good efficacy outcomes for contraception. Good safety outcomes for bleeding control and tolerability

■ Fuji's Strategy

- Series of product candidates through alliances with Alvotech
- Alvotech, which has many foreign sales partners, is highly cost competitive
- Since more stable supply is required than GE, Fuji plans to have manufacturing capability both overseas and domestically

■ Market

- In recent years, sales of biopharmaceuticals have expanded rapidly. Biopharmaceuticals are generally expensive, which is said to be one of the factors contributing to increased medical costs.
- As biopharmaceuticals face patent cliffs, biosimilar penetration is essential to reduce medical costs.
- The Pharmaceutical Industry Vision 2021 sets numerical targets for promoting the use of biosimilars, and discussions are underway to establish incentives for BS penetration.

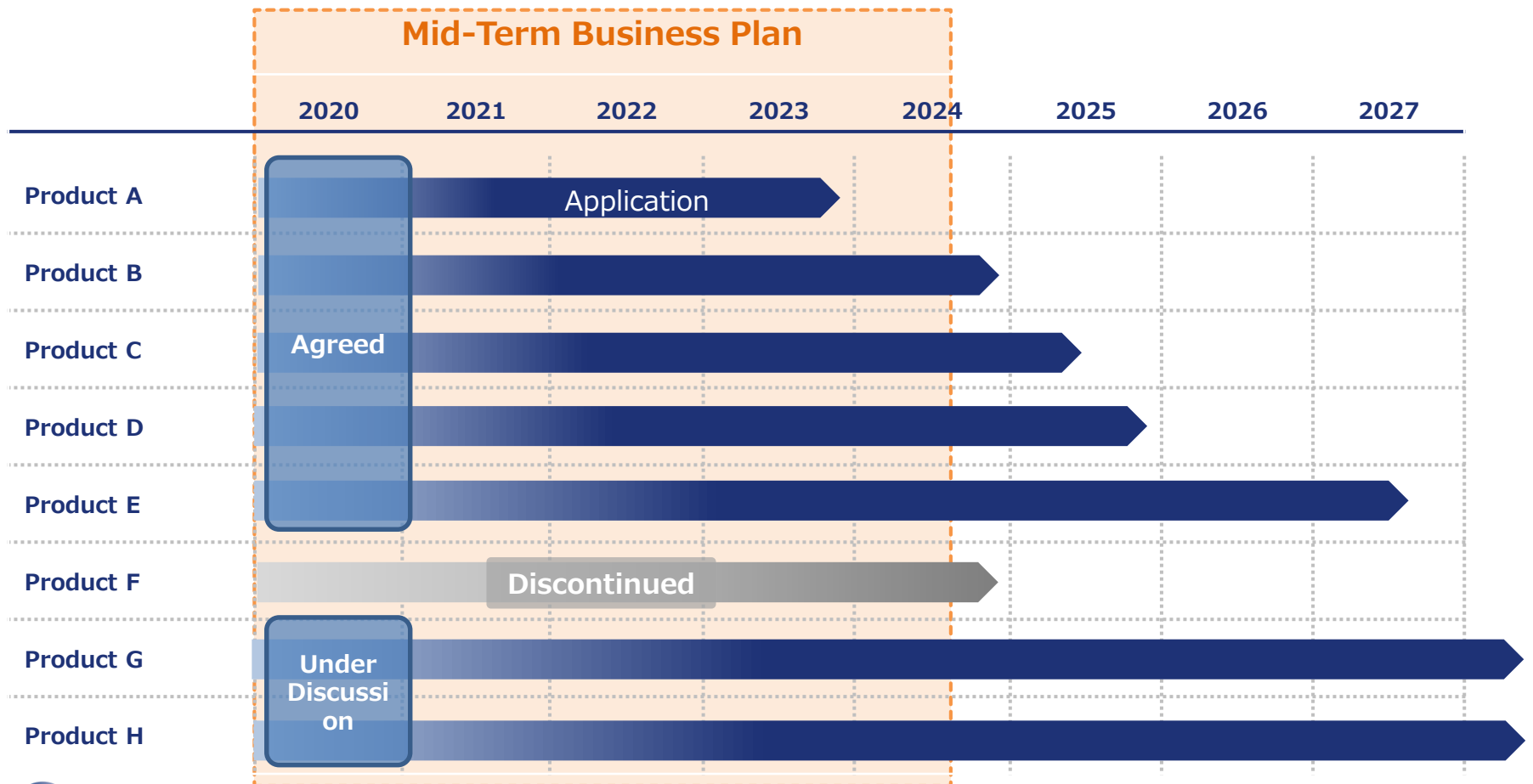


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Source : EvaluatePharma "World Preview2020"

5 BS ~Pipelines

- Following the partnership agreement with Alvotech to commercialize biosimilars in Japan (Nov. 2018), we discussed seven drugs for autoimmune diseases, malignant neoplastic diseases, etc. (total market size in Japan: 250 billion yen).
- Among them, five products have been agreed, and the market size of five products is approximately JPY 200 billion.
- Additional 1 product was added to start examination of 3 products, of which 1 product was discontinued development, and discussions continued for 2 products (total market size in Japan : JPY 130 billion)



Appendix

Summary of consolidated financial statements for the past five periods (comparison of old and new accounting standards)

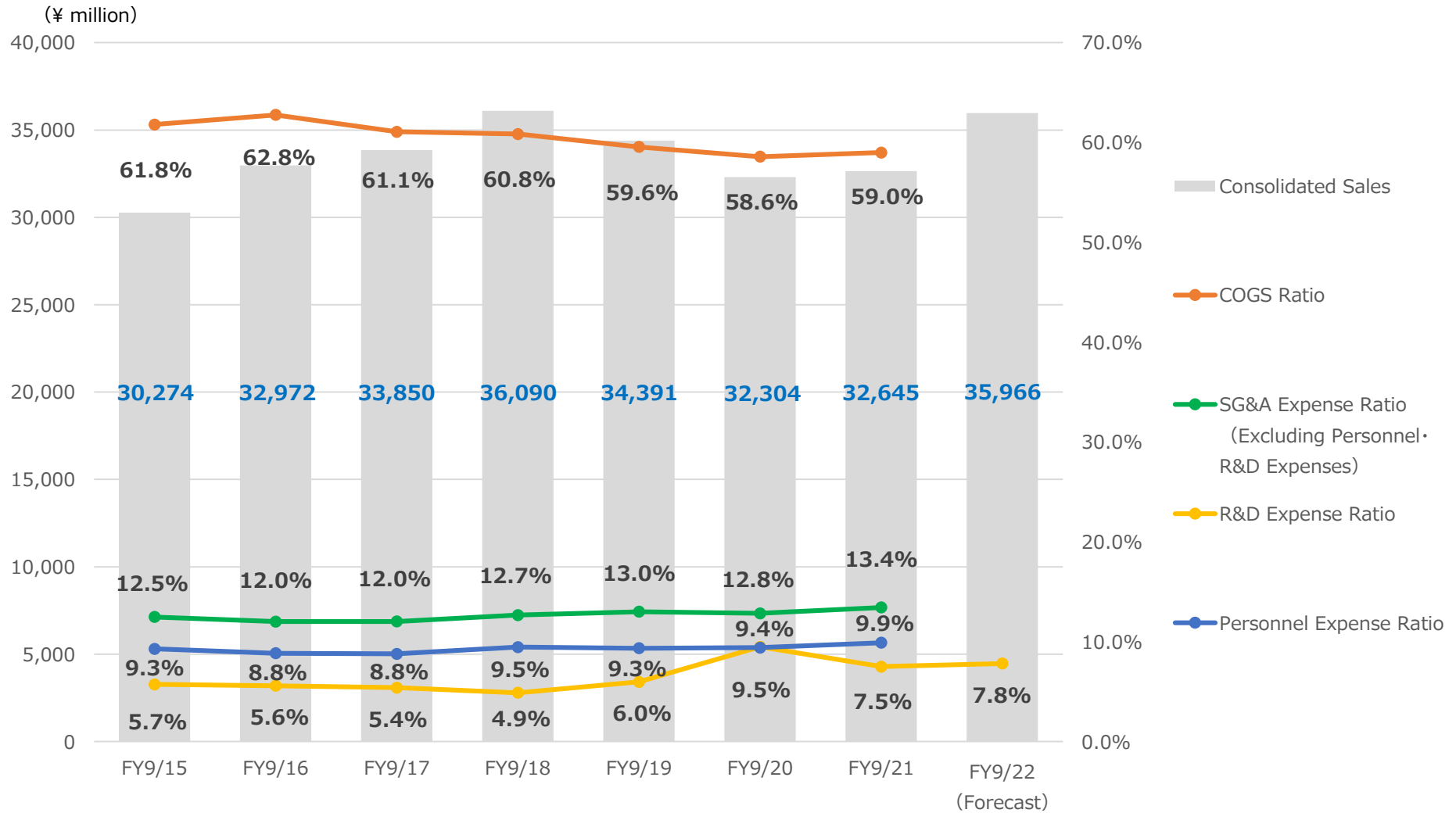
New accounting standards (¥million)	FY9/17	FY9/18	FY9/19	FY9/20	FY9/21
	Full Year	Full Year	Full Year	Full Year	Full Year
Net Sales	33,850	36,090	34,391	32,304	32,645
Gross Profit	13,178	14,131	13,908	13,382	13,406
Gross Margin	38.9%	39.2%	40.4%	41.4%	41.1%
SG&A Expenses	8,863	9,740	9,734	10,243	10,056
SG&A Margin	26.2%	27.0%	28.3%	31.7%	30.8%
Operating Profit	4,314	4,391	4,173	3,139	3,349
Operating Margin	12.7%	12.2%	12.1%	9.7%	10.3%
Ordinary Profit	4,628	4,472	4,169	2,983	3,250
Ordinary Margin	13.7%	12.4%	12.1%	9.2%	10.0%
Profit Attributable to Owners of Parent	3,301	3,372	2,962	2,085	2,432
Profit Margin	9.8%	9.3%	8.6%	6.5%	7.4%

Old accounting standards (¥million)	FY9/17	FY9/18	FY9/19	FY9/20	FY9/21
	Full Year	Full Year	Full Year	Full Year	Full Year
Net Sales	35,387	37,909	36,279	33,793	33,990
Gross Profit	14,715	15,950	15,796	14,872	14,751
Gross Margin	41.6%	42.1%	43.5%	44.0%	43.4%
SG&A Expenses	10,401	11,559	11,622	11,732	11,402
SG&A Margin	29.4%	30.5%	32.0%	34.7%	33.5%
Operating Profit	4,314	4,391	4,173	3,139	3,349
Operating Margin	12.2%	11.6%	11.5%	9.3%	9.9%
Ordinary Profit	4,628	4,472	4,169	2,983	3,250
Ordinary Margin	13.1%	11.8%	11.5%	8.8%	9.6%
Profit Attributable to Owners of Parent	3,301	3,372	2,962	2,085	2,432
Profit Margin	9.3%	8.9%	8.2%	6.2%	7.2%

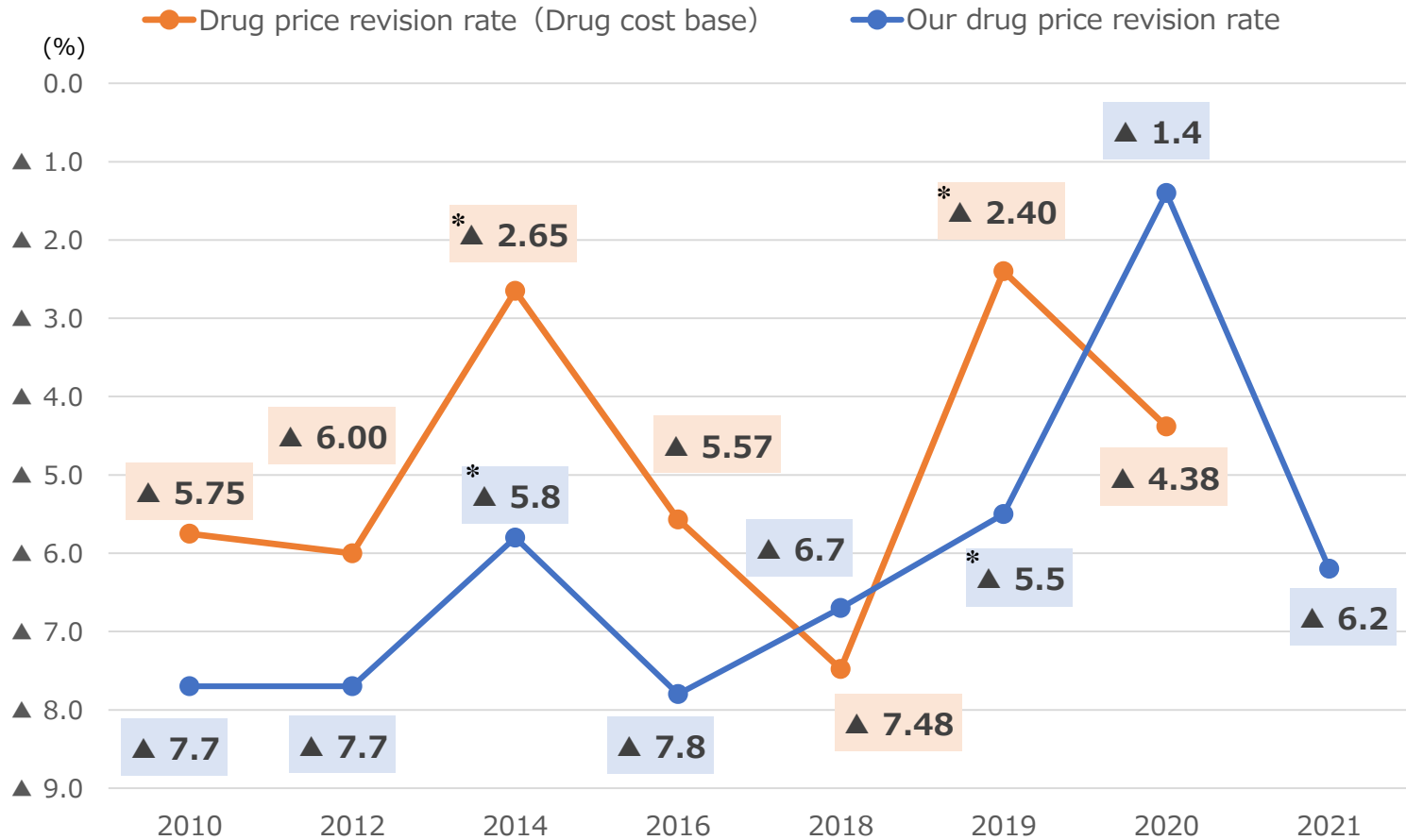
* Yellow: where numbers are different



COGS, SG&A, and R&D expenditure ratios trends (New accounting standards)

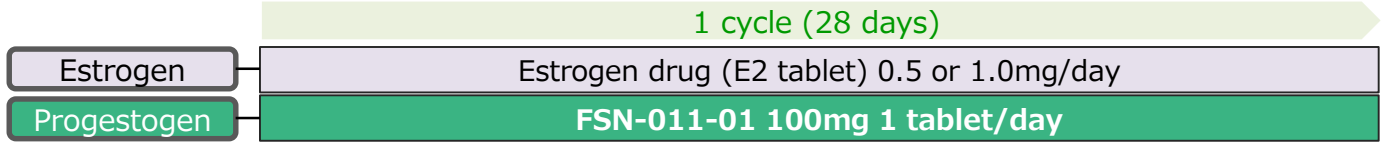
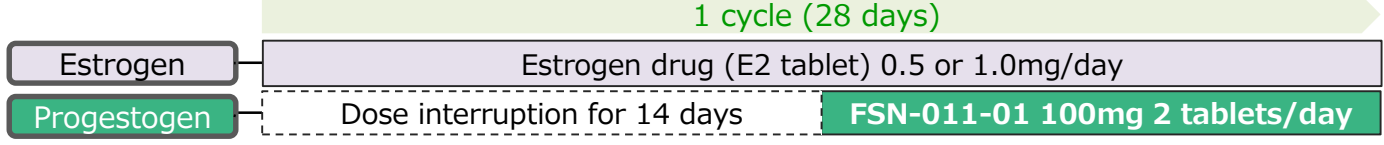


Impact of Drug price revisions

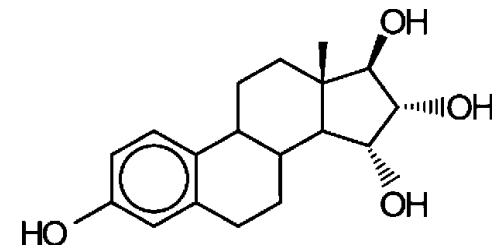


* : Including an increase due to consumption tax hike

FSN-011-01 : Outline of Japan Phase III Clinical Study

Test Purpose	To evaluate inhibitory effect of endometrial hyperplasia and safety of FSN-011-01 given with estrogen preparation in Japanese women with menopausal disorder with uterus or women with ovarian deficiency symptoms to undergo hormone replacement therapy
Design	Non-randomized, multicenter, open trial
Number of cases	328 cases (161 cases in continuous administration method group and 167 cases in periodic administration method group)
Subject	Patients with uterus between the ages of 40 and 65 who are receiving or are eligible for hormone replacement therapy
Dosage and administration	<p>Oral administration before bedtime for 52 weeks</p> <p>① From day 1 to day 28, administer 100 mg of FSN-011-01 once daily (1 cycle=28 days)</p>  <p>② From day 15 to day 28, administer 200 mg of FSN-011-01 once daily (1 cycle=28 days)</p> 
Evaluation items	<p>Primary endpoint : Incidence of endometrial hyperplasia without atypia</p> <p>Secondary endpoint : Thickness of endometrium during the dosing period</p> <p>Safety endpoint : Incidence of adverse events and adverse drug reactions</p>
Result	No endometrial hyperplasia without atypia was observed with any administration methods

- ❑ Estetrol was discovered in the urine of pregnant women at the 1965 Karolinska Institute.
- ❑ Produced in the liver of higher primate fetuses and translocated through the placenta into the maternal body.
Is distributed in fetal plasma at 12-fold the maternal concentration and in the body is detected in maternal urine from week 9 of gestation.
- ❑ Estrogenic activity of estetrol is weaker than that of other estrogen, ethinylestradiol and estradiol.
- ❑ Relative to its affinity for ER β is 4-to 5-fold more affinity for ER α .
- ❑ Estetrol selectively activates nuclear ER α (membrane ER α is not activated).
- ❑ With these selectivities, various benefits are expected.
- ❑ This is called Natural Estrogen with Selective Action in Tissues (NEST)



Structure of Estetrol

FSN-013 : Outline of Japan Phase II (Study No. FSN-013-05)

Test Purpose	A total of 28 days of administration of FSN-013(Estetrol [E4] 15 mg/drospirenone [DRSP] 3 mg combination tablet) for 24 days followed by placebo tablets for 4 days in patients with endometriosis are taken as one cycle. After administration for 3 cycles, to investigate the pain-improving effects and the pharmacodynamic, pharmacokinetic, and safety effects on the hemocoagulation fibrinolytic system and the endocrine system.
Design	Multicenter, open-label, randomized, parallel group
Number of cases	80 cases(40 per group)
Subject	Patients with endometriosis
Dosage and administration	<p>①The test drug (E4 15 mg/DRSP 3 mg combination tablets) will be administered for 24 days, followed immediately by a placebo tablet for 4 days. A total of 28 days is set as 1 cycle, and a total of 3 cycles(84 days) are administered.</p> <p>②Reference drug [Ethinyl estradiol (EE) betadex 0.020mg/DRSP 3 mg combination tablet] is administered continuously with or without hemorrhage until day 24. If hemorrhage (including punctate hemorrhage) is observed for 3 consecutive days after day 25, the drug is withdrawn for 4 days. Continuous dosing is started after withdrawal, regardless of whether bleeding has ended or persists, and is given for 84 days.</p>
Evaluation items	<ul style="list-style-type: none"> • Pharmacodynamic effect <ul style="list-style-type: none"> - The most advanced pelvic pain (lower abdominal and lower back pain) VAS, etc. - Gynecologic examination items - Blood coagulation-fibrinolysis system-related parameters - Endocrine-related parameters • Safety <ul style="list-style-type: none"> - Incidence of adverse events and adverse drug reactions

Note on forecast and prospects

The financial forecasts and other projections provided in this presentation are based on information available at the time of its compilation and it therefore contains an element of uncertainty and potential risks.

Actual results may differ significantly from these forecasts for a number of reasons.

It should also be noted that the views and/or facts presented here may be altered or deleted without prior notification.

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