Fuji Pharma Co., Ltd.

FY9/2021 Investor Meeting

November 18, 2021

Event Summary

[Company Name]	Fuji Pharma Co., Ltd.
[Company ID]	4554-QCODE
[Event Language]	JPN
[Event Type]	Earnings Announcement
[Event Name]	FY9/2021 Investor Meeting
[Fiscal Period]	FY2021 Annual
[Date]	November 18, 2021
[Number of Pages]	45
[Time]	16:00 – 16:59 (Total: 59 minutes, Presentation: 43 minutes, Q&A: 16 minutes)
[Venue]	Webcast
[Venue Size]	
[Participants]	
[Number of Speakers]	4

Takayuki Iwai	President & CEO
Atsuya Mitsuhashi	Executive Corporate Officer, Head of Portfolio Management Department
Masayuki Naganawa	Corporate Officer, Vice General Manager of Research & Development Division
Takeshi Sato	Corporate Officer, General Manager of Corporate Planning Department

Presentation

Moderator: Good afternoon, everyone. Thank you very much for participating in today's presentation of the financial results for Fuji Pharma for the fiscal year ending September 30, 2021.

First, I would like to introduce today's speakers.

Mr. Takayuki Iwai, President and CEO.

Iwai: This is Iwai. Thank you.

Moderator: Mr. Atsuya Mitsuhashi, Executive Corporate Officer, Head of Portfolio Management Department.

Mitsuhashi: This is Mitsuhashi. Thank you.

Moderator: Mr. Masayuki Naganawa, Corporate Officer, Vice General Manager of Research and Development Department.

Naganawa: I am Naganawa. Thank you.

Moderator: Mr. Takeshi Sato, Corporate Officer, General Manager of Corporate Planning Department.

Sato: I'm Sato. Thank you.

Moderator: As for today's proceedings, Mr. Iwai and Mr. Sato will provide an overview of the financial results for the fiscal year ended September 30, 2021, the forecast for the fiscal year ending September 30, 2022, and the progress of Mid-term Business Plan.

We will then proceed to the Q&A session. We will take as many questions as time permits, so please feel free to send any questions you have. You can post questions at any time, even during the presentation.

We will now move on to the financial results presentation. Thank you very much, Mr. Iwai.

Agenda

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**

Iwai: Hello. Thank you very much for taking time out of your busy schedule to join us today.

Today, we would like to talk about these 4 points.

First, Mr. Sato will provide an overview of the consolidated financial results for the fiscal year ended September 30, 2021 and the consolidated earnings forecast for the fiscal year ending September 30, 2022.

FY9/21 Financial Result Highlights

- **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

Sato: Thank you. I will now give an overview of the consolidated financial results for the fiscal year ended September 30, 2021 and the consolidated earnings forecast for the fiscal year ending September 30, 2022.

In the fiscal year ending September 30, 2021, solid sales in the field of women's healthcare offset the decline in sales of diagnostic drugs. This decline mainly affected contrast media, and was due to NHI price revision and COVID-19 impact.

Expenses decreased by 2.8% compared to the previous fiscal year, as R&D expenses were lower than expected, and we were able to control sales commissions.

OLIC suffered from a decline in orders due to COVID-19 impact. Although performance was better than we had forecast, a decrease in sales during the period was recorded.

Operating profit increased by JPY210 million, or 6.7%, from the previous fiscal year.

In research and development, we received approval in September 2021 for FSN-011-01, product name F-meno® Capsules.

We started Phase III trials in Japan for FSN-013 in August 2021, while in ASEAN, we filed for import approval in Thailand in September.

FY9/21 Consolidated Financial Results

- Net Sales : Iincreased 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 Full Year	**FY9/21 Full Year**	YoY Change Amount	YoY Change Ratio	FY9/21 Forecast	vs Fcst 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%	

5

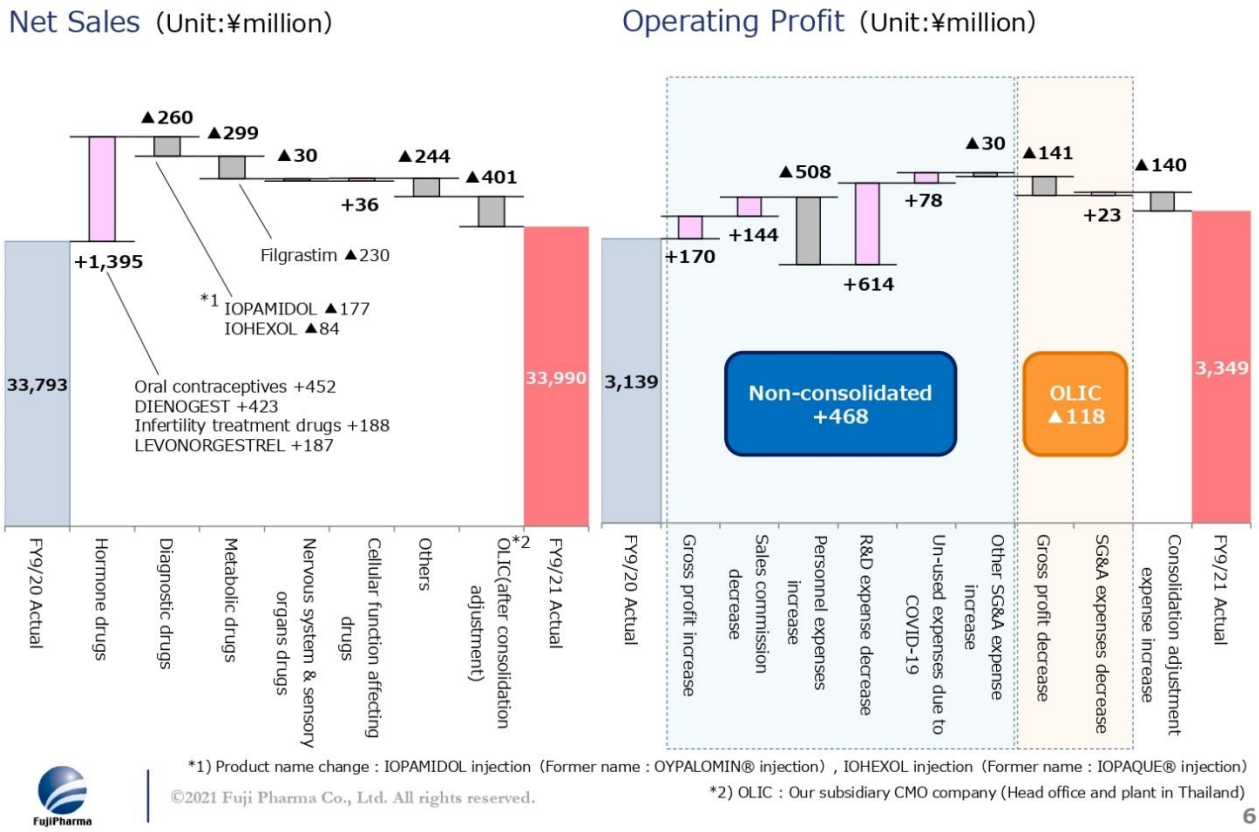
I will talk about the analysis of the difference between net sales and operating profit in a later slide. Here, I will talk about gross margin, capital expenditure, and R&D expenses.

First, the gross margin. Although there was an improvement in terms of product mix due to growth in the area of women's healthcare and a decrease in contrast media, overall performance deteriorated by 0.8%. This was due to the impact of the NHI price revision in April 2021 and the fixed cost burden caused by the drop in sales of diagnostic drugs.

Next, capital expenditure increased slightly. The main target of expenditure was a new tablet building at the Toyama Plant. The large difference from the planned amount is due to a change in the timing of payments. There have been no overall changes to our capital expenditure plan.

Finally, R&D expenses decreased significantly compared to both the previous fiscal year and the forecast figure. This is due to a combination of factors, including the high cost of Phase III trials for new drug development in the previous fiscal year, efforts to reduce development-related expenses, and the fact that expenditures for some products were delayed.

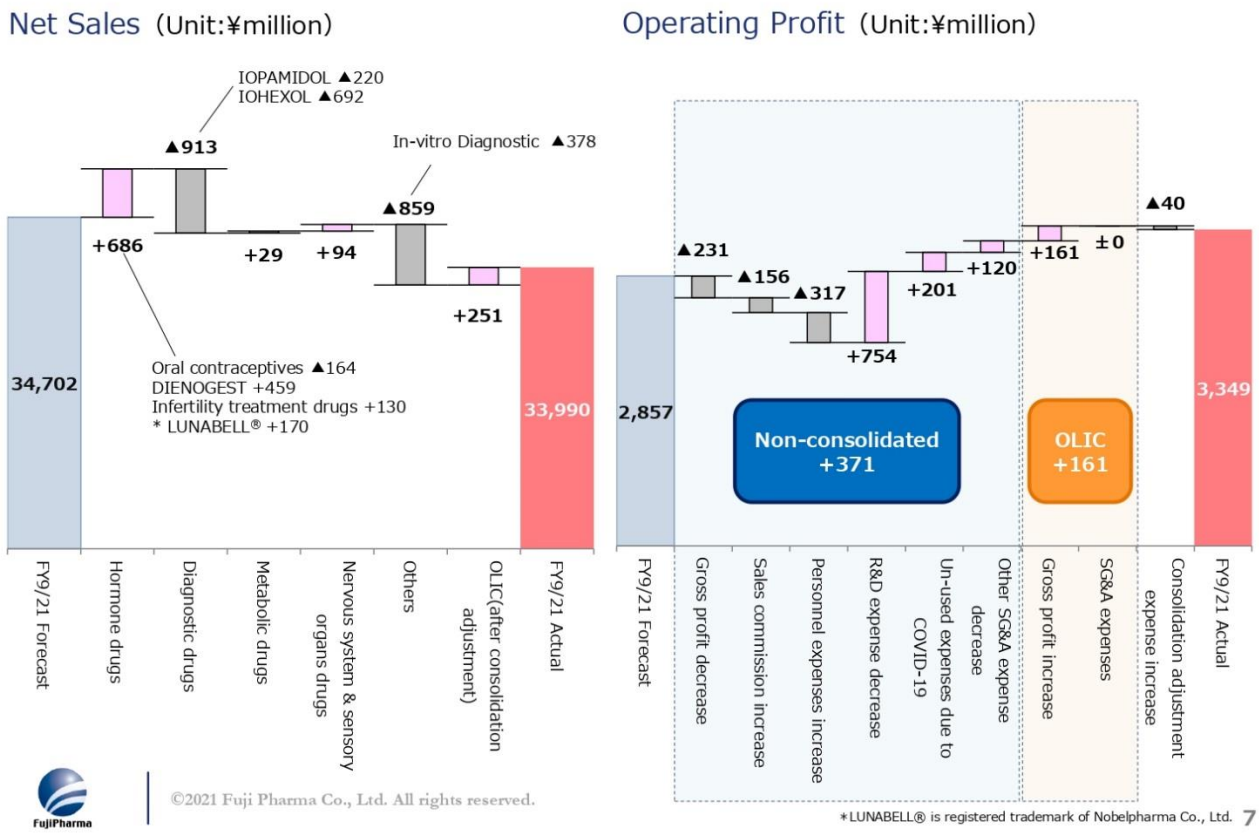
FY9/21 Consolidated Financial Results (YoY)



This is an analysis of the differences between the previous fiscal year and the fiscal year ending September 30, 2021.

For sales, please see the chart on the left. As I mentioned in the highlights, sales of hormone drugs in the field of women's healthcare grew significantly, while sales of contrast media and OLIC decreased due to COVID-19 impact. In spite of the NHI price revision in April 2021, we were able to achieve a small YoY increase in sales.

For operating profit, please see the chart on the right. The combined effect of controlling sales commissions, the decrease in R&D expenses, and the control of expenses due to COVID-19 was a positive effect on profits of approximately JPY800 million. There was an increase of approximately JPY500 million in personnel expenses due to performance-linked compensation, resulting in an overall increase of JPY210 million.



This is a reanalysis compared to the initial forecast.

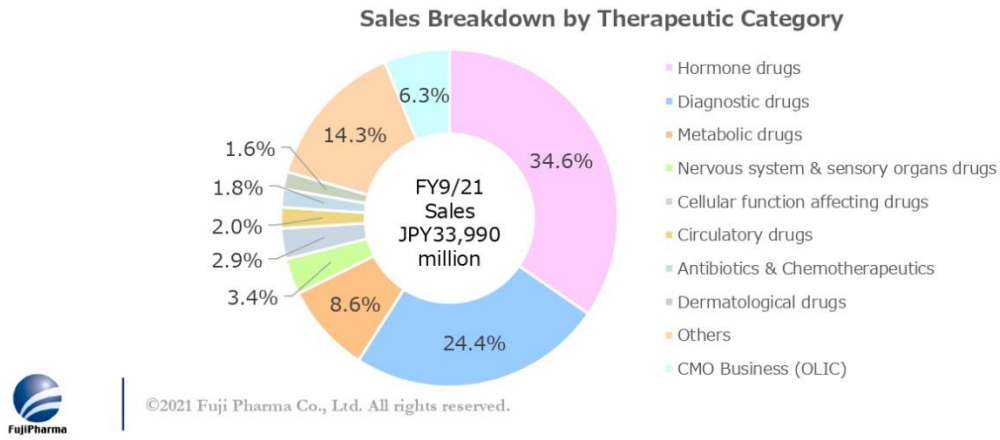
The chart for sales is on the left. With regard to contrast media, we had planned to increase sales through sales activities even during COVID-19 impact. However, the prolonged COVID-19 impact and the impact of the NHI price revision, which was larger than expected in the second half of the fiscal year, have resulted in difficult results. In addition, anti-coronavirus measures resulted in low numbers of influenza cases, which also resulted in a decrease in revenue. Although sales in the area of women's healthcare were strong and one-time income accumulated in OLIC compensated for the decline elsewhere due to COVID-19, sales decreased compared to the forecast.

For operating profit, please see the chart on the right. As you can see, the reduction in R&D expenses during COVID-19 impact absorbed the increase in personnel expenses due to sales commissions and performance-linked compensation. This resulted in a significant increase in profit compared to the forecast.

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%
Of which, CMO Business (FUJI)	*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



8

I will explain sales by drug class.

Sales of hormone drugs, which account for the largest share of sales, grew significantly. This was supported by continued strong demand in the field of women's healthcare. In addition, contract sales at the Toyama Plant also grew, despite difficult conditions for non-hormone drugs.

Sales of Major Products

Product Name (¥million)	Therapeutic Category	FY9/17	FY9/18	FY9/19	FY9/20	**FY9/21**	YoY Change Amount	YoY Change Ratio	FY9/21 Budget
★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	1,671	1,721	1,974	2,299	**2,069**	▲ 230	-10.0%	2,099
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®	Nervous system & sensory organs drugs	-	-	-	1,104	**1,092**	▲ 12	-1.1%	1,009
Labellefille® tablets	Hormone drugs	398	526	709	862	**1,002**	140	16.2%	1,171
LUNABELL® tablets (LD/ULD)	Hormone drugs	2,845	2,769	1,583	1,045	**978**	▲ 67	-6.4%	808
DEXART® injection	Hormone drugs	866	870	894	874	**961**	87	9.9%	913
◆UTROGESTAN® vaginal capsules	Hormone drugs	578	649	788	712	**889**	177	24.8%	859
◆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®	Hormone drugs	474	480	451	404	**422**	18	4.2%	461
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

9

This is net sales of major products.

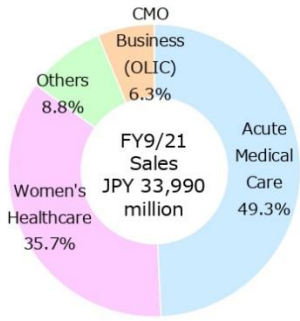
Here, too, sales of hormone drugs in the field of women's healthcare increased across the board compared to the previous fiscal year. In particular, sales of oral contraceptives such as Favoir® and Labellefille®, and sales of endometriosis Treatment drug such as DIENOGEST are growing. Diamond-mark infertility treatment drugs are also growing significantly. The supply of FOLYRMON®-P injection, which was previously listed here, resumed on November 5.

Sales by Medical Field and Dosage Form Category

Medical Field Category (¥million)	FY9/17	FY9/18	FY9/19	FY9/20	**FY9/21**	YoY Amount	YoY 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	YoY 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

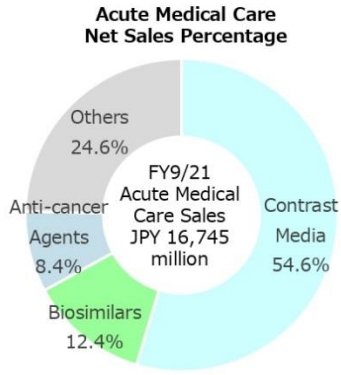
10

I would like to provide a supplementary explanation about the top right pie chart.

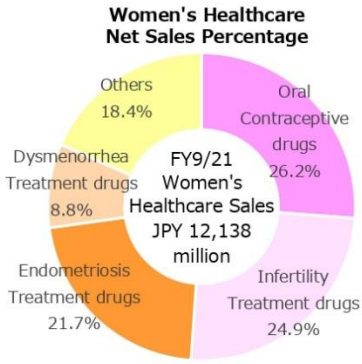
The percentage for acute medical care had been above 50% until the fiscal year ending September 2020, but due to the growth in sales in the area of women's healthcare, the percentage is now below 50%.

Sales of Acute Medical Care and Women's Healthcare

Acute Medical Care (¥Million)	FY9/17	FY9/18	FY9/19	FY9/20	**FY9/21**	YoY Amount	YoY 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 (¥Million)	FY9/17	FY9/18	FY9/19	FY9/20	**FY9/21**	YoY Amount	YoY 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%



Next, I'll say a few more words about the bottom right pie chart.

In the past, infertility treatment drugs were the largest category, but the growth of oral contraceptives was so large that the pattern reversed in the last fiscal year. As you can see, sales of oral contraceptives have more than tripled over the past 5 years.

FY9/21 Summary of Consolidated Balance Sheet

(¥million)	FY9/20 Year End	**FY9/21 Year End**	YoY Change Amount	YoY Change 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 Liabilites 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

12

The balance sheet as of the end of the fiscal year ending September 30, 2021 is shown here.

Beside the Capex on Toyama plant, including the lease, the major change is the change in the capital and liability structure due to the acquisition and cancellation of treasury stock in February and March.

FY9/21 Summary of Consolidated Statements of Cash Flows

(¥million)	FY9/20 Year End	**FY9/21 Year End**	YoY Change Amount	YoY Change 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

13

This is the cash flow.

We have already talked about the acquisition and cancellation of treasury stock.

Cash flow from investing activities related to the new tablet building at the Toyama Plant, the construction is progressing as planned. In the previous fiscal year, we sold all domestically listed shares among cross-shareholdings.

FY9/22 Consolidated Forecast Highlights

- **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

15

Now, I would like to talk about the consolidated earnings forecast for the current fiscal year ending September 30, 2022.

In the current fiscal year, we plan to increase both sales and profits for the second consecutive year.

Net sales are expected to increase due to the new F-meno® Capsules, the newly in-licensed product PROPESS®, existing products in the field of women's healthcare centered 6 key products, and the expected contribution OLIC recovers from results seen during COVID-19 impact.

Operating profit is expected to increase due to the increase in net sales, which will offset the increase in R&D and SG&A expenses.

In addition, we plan to increase dividends for the first time in 3 fiscal years, in accordance with our policy of a dividend payout ratio of 30%.

In the area of research and development, we will proceed with Phase III trials of FSN-013 in Japan and import approval procedures in Thailand.

With regard to biosimilars, we are preparing to file for the first round of approval through our alliance with Alvotech within this fiscal year.

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	FY9/22	YoY Change		reference FY9/21 Old accounting standards
	Actual	Forecast	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 (Inclusind 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.

16

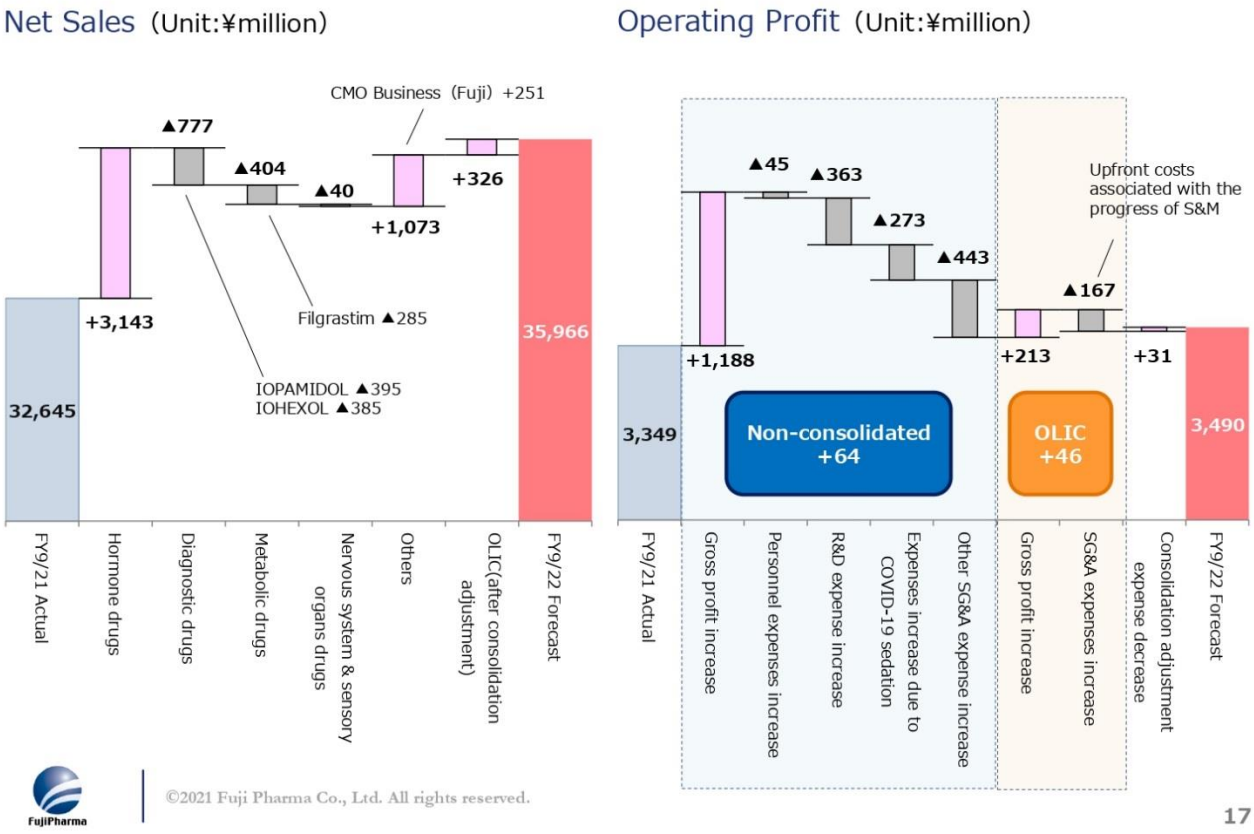
The sales forecast for this fiscal year is JPY36 billion, up 10.2% from the previous fiscal year. The main contributors will be the new women's healthcare drug F-meno® Capsules, the in-licensed PROPESS® and existing 6 key products.

Forecast operating profit increases 4.2% YoY to JPY3.5 billion. The operating margin is expected to decrease slightly due to an expected increase in R&D and SG&A expenses.

Capital expenditure will increase substantially due to plans to expand Capex facilities in Japan, including a new tablet building at the Toyama Plant.

R&D expenses are planned to increase by 14.8% to JPY2.8 billion. In the previous fiscal year, actual results fell significantly short of the initial forecast. In the current fiscal year, we will continue to promote R&D activities firmly toward the launch of new products, while controlling costs as necessary.

Summary of FY9/22 Consolidated Forecast (YoY)



The chart on the left shows the factors behind the change in forecast net sales for the current fiscal year.

Sales of hormone drugs are planned to increase substantially to JPY3.1 billion. In addition, the Toyama Plant and the OLIC CMO business are also anticipated to see increase sales. This will offset the decrease in sales of contrast media and other products, resulting in the planned increase in sales.

In hormone drugs, the plan is to increase sales mainly due to a combination of several factors, including, F-meno® Capsules, the in-licensed PROPESS®, existing products centered 6 key main products, and infertility treatment drugs that are expected to be covered by insurance.

Operating profit for the fiscal year is expected to increase. This is because the increase in revenue will offset the increase in R&D expenses and expenses due to COVID-19 sedation.

Sales Forecast by Therapeutic Category and Medical Field

(¥million)	FY9/21 Actual	**FY9/22 Forecast**	YoY Change Amount	YoY Change 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%
Including CMO Business (FUJI)	*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 Actual	**FY9/22 Forecast**	YoY Amount	YoY 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

18

Here is a table showing the contents of the waterfall chart that I explained earlier.

You can see that hormone drugs and CMO business are growing.

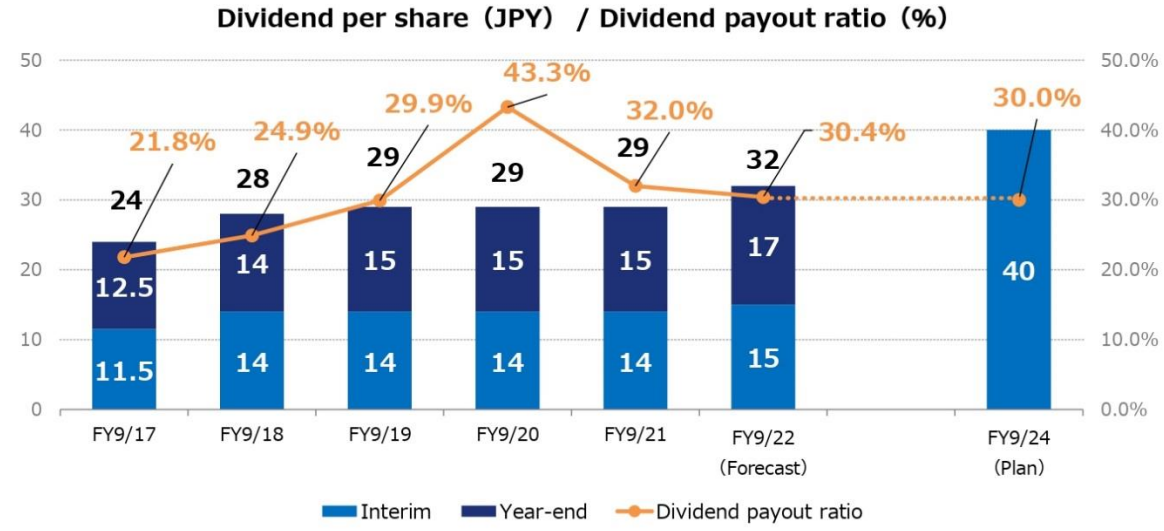
At this point, I would like to say that due to circumstances unique to this fiscal year, I will refrain from explaining the sales forecast for major products as in the past.

We are refraining from disclosing any information that might suggest the outlook for these products for the current fiscal year, as we are currently in the process of the NHI price listing of F-meno® Capsules, and the procedures for the insurance coverage of infertility treatment drugs in April 2022 are in progress.

In the future, we will make decisions based on the situation at the time, but we will do our best to disclose the results.

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)



※ 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.

19

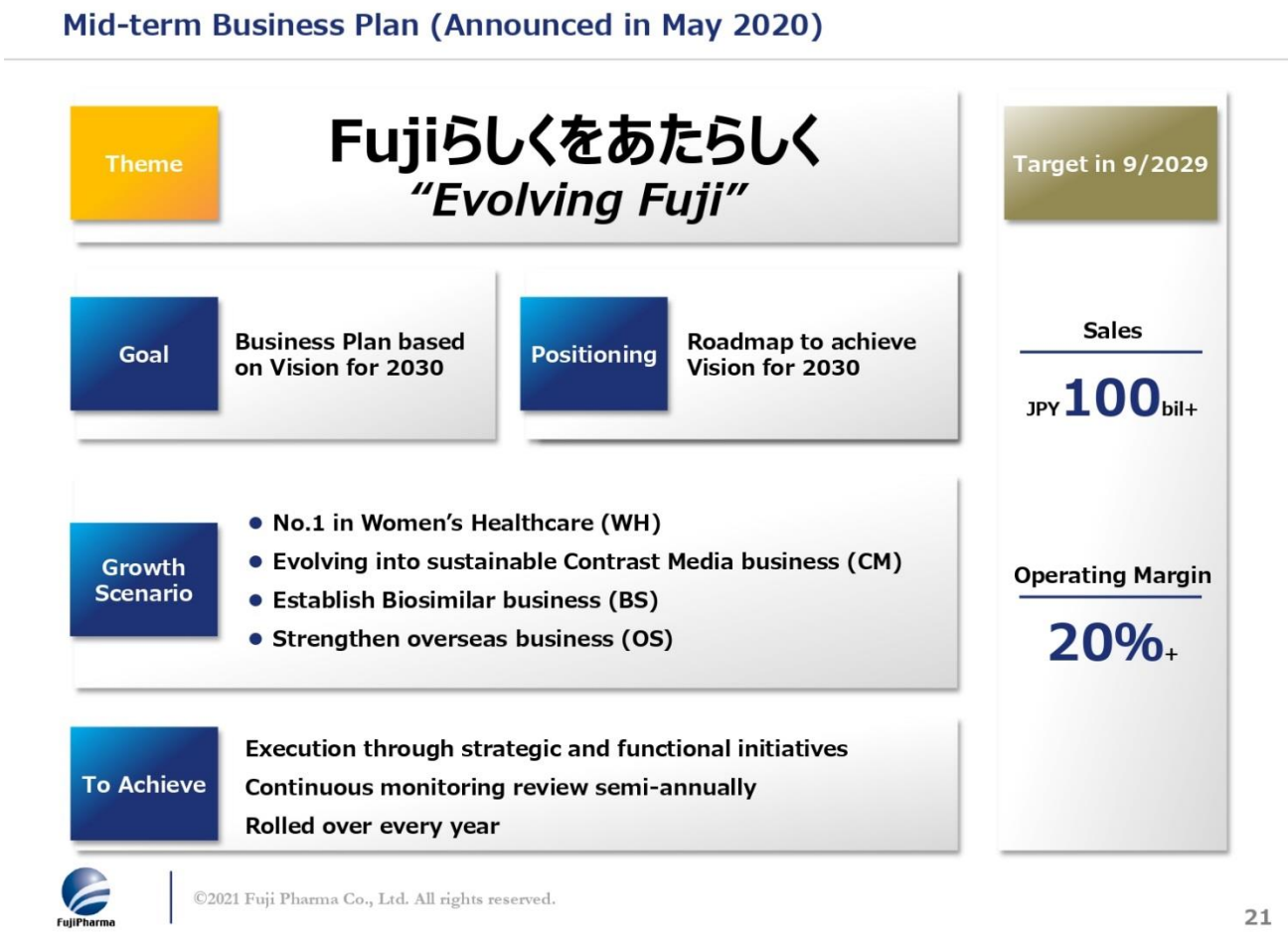
Lastly, I would like to talk about our shareholder return policy for the fiscal year ending September 30, 2022.

Our dividend policy is to achieve a dividend payout ratio of 30% with stable dividends. This is as explained in our Corporate Report and other documents. If profits for the current fiscal year reach the forecast level, we plan to pay 32 yen annual dividend by applying dividend payout ratio of 30%.

This concludes my presentation.

Next, Mr. Iwai will talk about Mid-term Business Plan.

Iwai: I would now like to explain the progress in Mid-term Business Plan in Chapter 3. We have several products that will be very important in achieving Mid-term Business Plan. These products are labeled with a number before the product name in Chapter 3. For these important products, we will explain positioning and product overview in Chapter 4.



Here is the overall picture of the current Mid-term Business Plan.

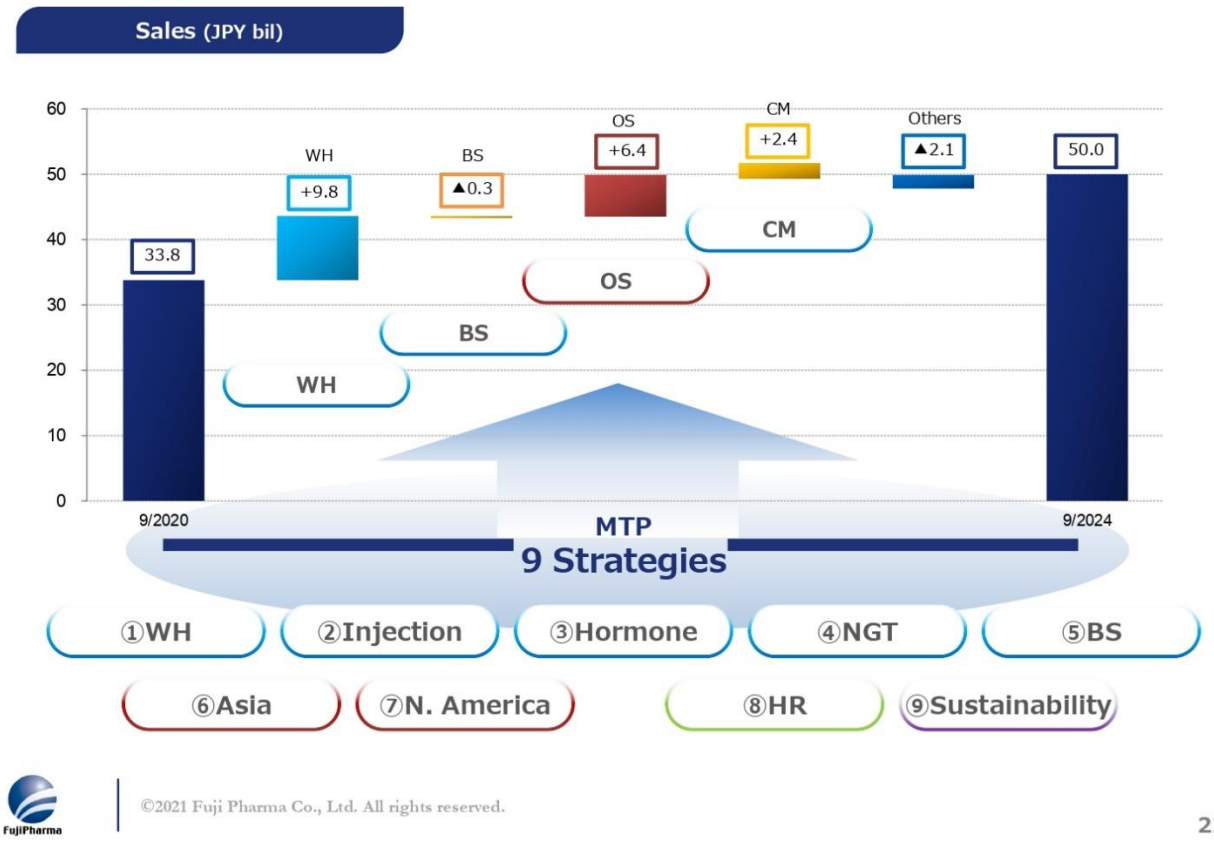
The current Mid-term Business Plan, which will end in the fiscal year ending September 30, 2024, is positioned as an intermediate point to achieve our goal of JPY100 billion in consolidated net sales in 10 years.

The 4 factors for achieving the goals of Mid-term Business Plan are shown here.

"No.1 in Women's healthcare" is the first point. The second is "Evolving into sustainable contrast media business". The third is "Establish Biosimilar business as a new pillar during the current Mid-term Business Plan with a view to the next Mid-term Business Plan." The fourth is "Strengthen overseas business centered on OLIC".

In the current Mid-term Business Plan, we will achieve JPY50 billion in the fiscal year ending September 2024 and build a solid foundation for achieving JPY100 billion in the fiscal year ending September 2029. I will explain this on the next page. This is the purpose and positioning of our Mid-term Business Plan.

In the fiscal year ending September 2024, as I mentioned, our sales target is JPY50 billion. There will be no change to this. We are currently working on a number of measures to achieve this goal.

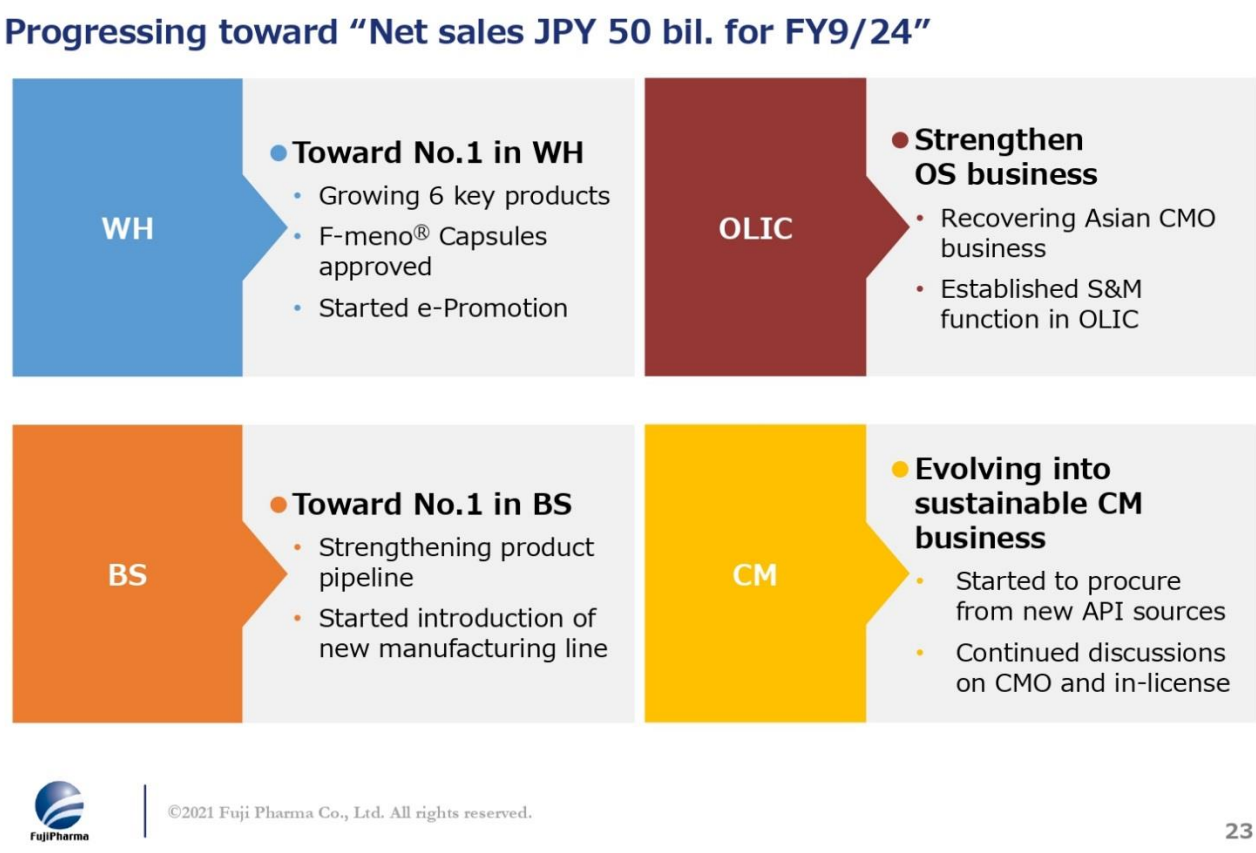


As you can see from this slide, there are 3 main initiatives to achieve the JPY50 billion target: first, women's healthcare, then the sustained contrast media business, and thirdly, overseas business centered on OLIC.

And to prepare for our goal of JPY100 billion in the next Mid-term Business Plan, we will make solid progress in the biosimilar business by the fiscal year ending September 2024.

In the next slide, I would like to explain the status of our efforts to date for each growth factor.

Summary of Progress in second half FY 9/21



Currently, we are making progress toward the FY2024 target as planned.

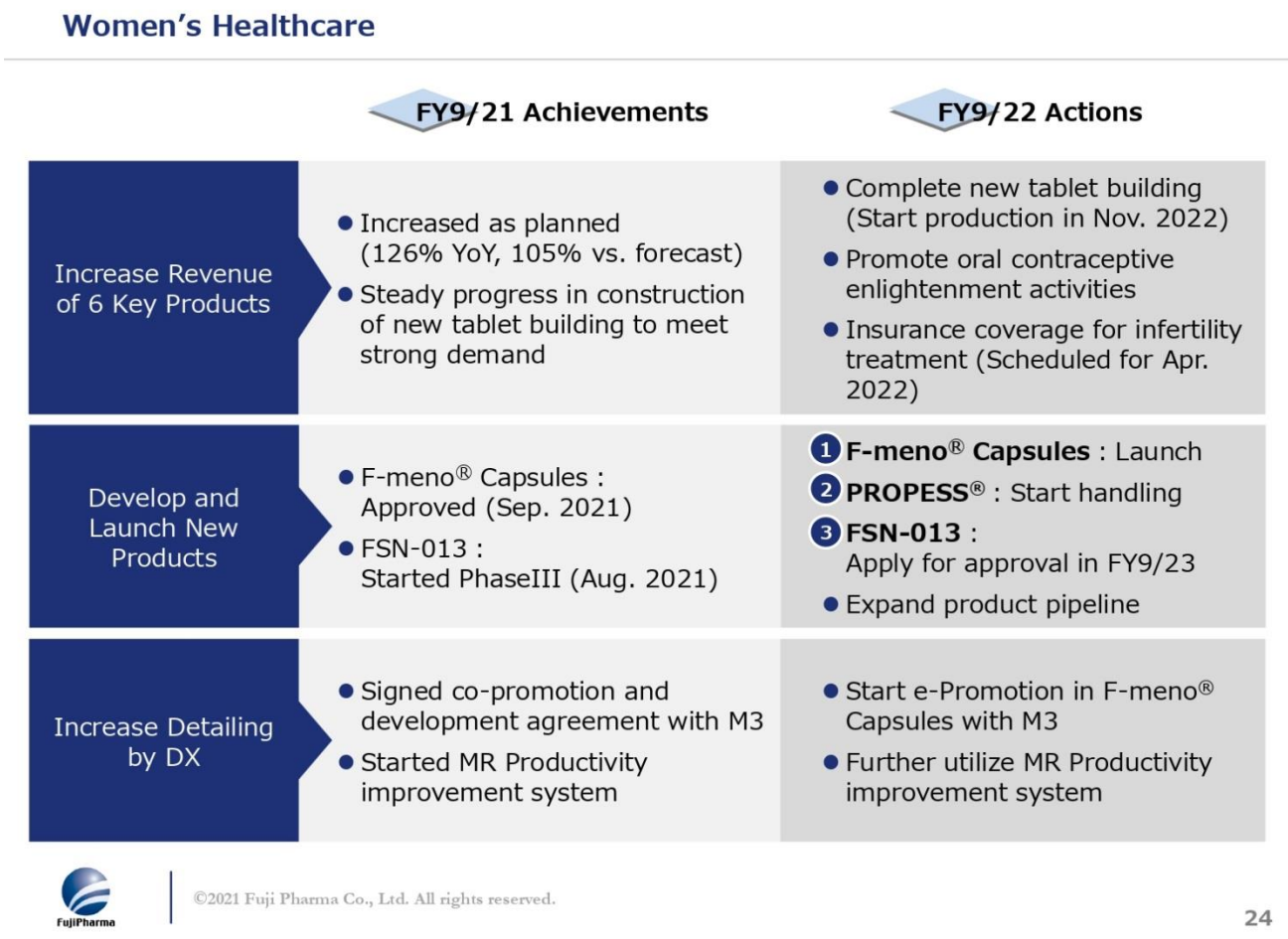
First of all, in the field of women's healthcare, the market for 6 key products is expanding steadily. Our products are making steady progress. In September of this year, we also received approval for F-meno® Capsules as planned. In the field of women's healthcare, we have already decided to start e-Promotion to further improve sales efficiency.

Next, in the overseas business of OLIC, the B2C CMO business, which had been declining in COVID-19 impact, is now on a recovery trend. In September this year, we filed an application for approval of FSN-013 in Thailand, which will be the core of the second business pillar, OLIC. We aim to start manufacturing and marketing our own products here.

We are also in the process of building up our pipeline of biosimilars.

In contrast media, we have started to procure new API sources and are actively considering CMO business from other companies.

In the next few slides, I would like to explain each area in more detail.



The first is women's healthcare. I would like to talk about 6 key products, new drugs, and the sales structure.

First of all, as mentioned earlier, the market for 6 key products is growing steadily. The sales of our products increased by 26% compared to the previous year. I would like to show you the sales of these 6 products in more detail in the next slide.

To meet this demand, we also began construction of a new tablet building at the end of last year. Construction is now well underway. Once completed, the new building will triple our current manufacturing capacity. We are determined to meet the immediate increase in demand by moving forward with the construction of these buildings.

In addition, compared to other countries in Europe and the United States, the use of hormone preparations for women is still quite low. We also plan to continue our enlightenment activities regarding the use of this product.

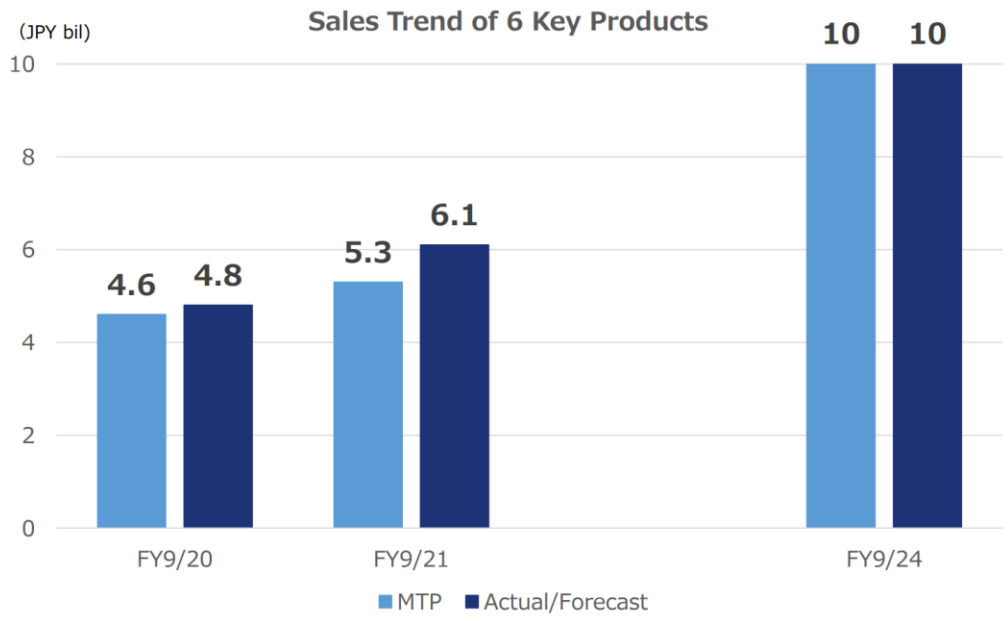
Next, regarding the development status of new drugs, as reported earlier, we received approval at the end of September for F-meno® Capsules. And Phase III trials for FSN-013 started in August this year as planned.

This month, on November 4th, we announced that we have agreed to collaborate in Japan with Ferring Pharmaceuticals for a product called PROPESS®.

These 3 products will be explained in detail in Chapter 4.

Last but not least, we have decided to introduce e-Promotion to improve MR productivity, and we intend to make use of it in the future.

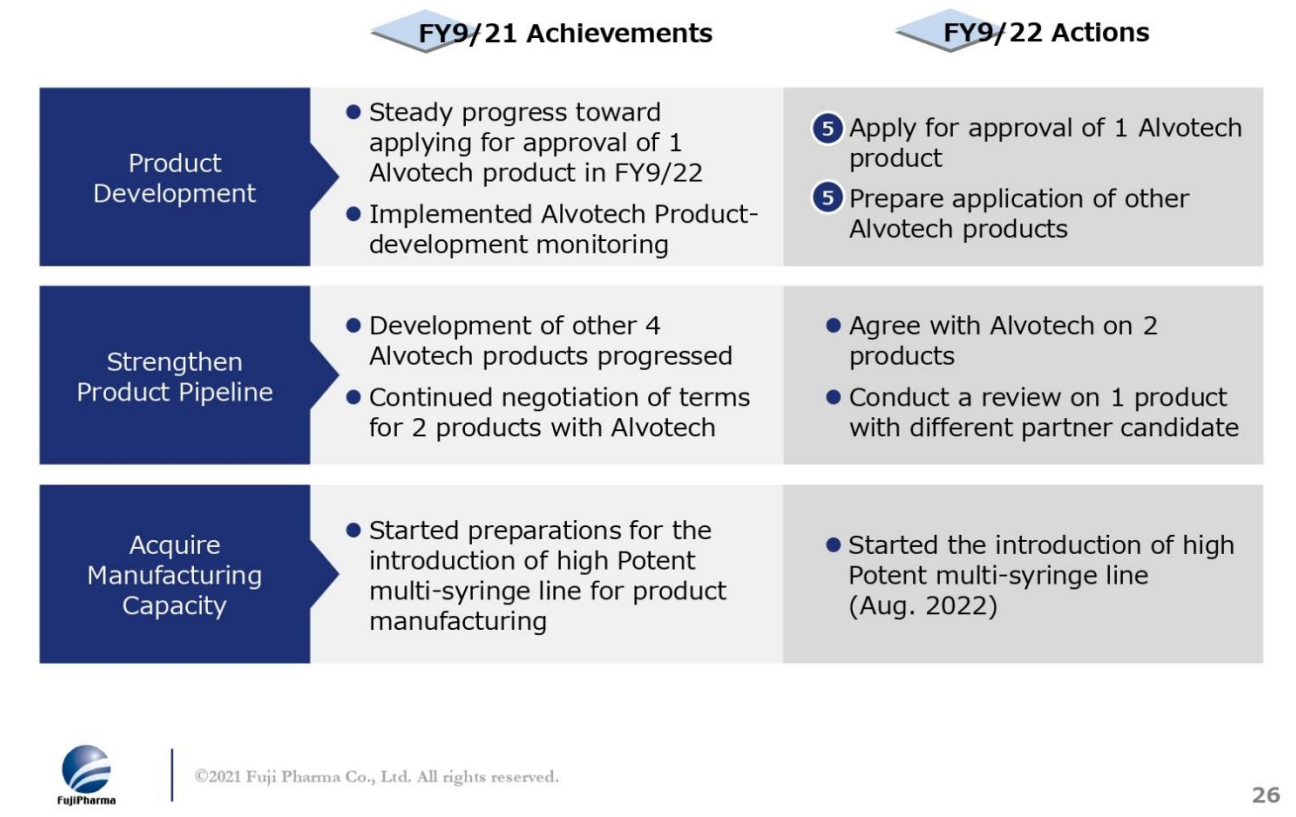
Women's Healthcare ～6 Key Products



This is the sales trend of 6 key products I mentioned in the previous slide.

The blue graph on the left is the sales forecast at the time of Mid-term Business Plan was formulated, and the darker blue graph on the right is the actual results and the current sales forecast for the fiscal year ending September 2024.

As shown in the graph, 6 key products are performing well, and we expect to achieve the target for the fiscal year ending September 30, 2024.



The second is biosimilars.

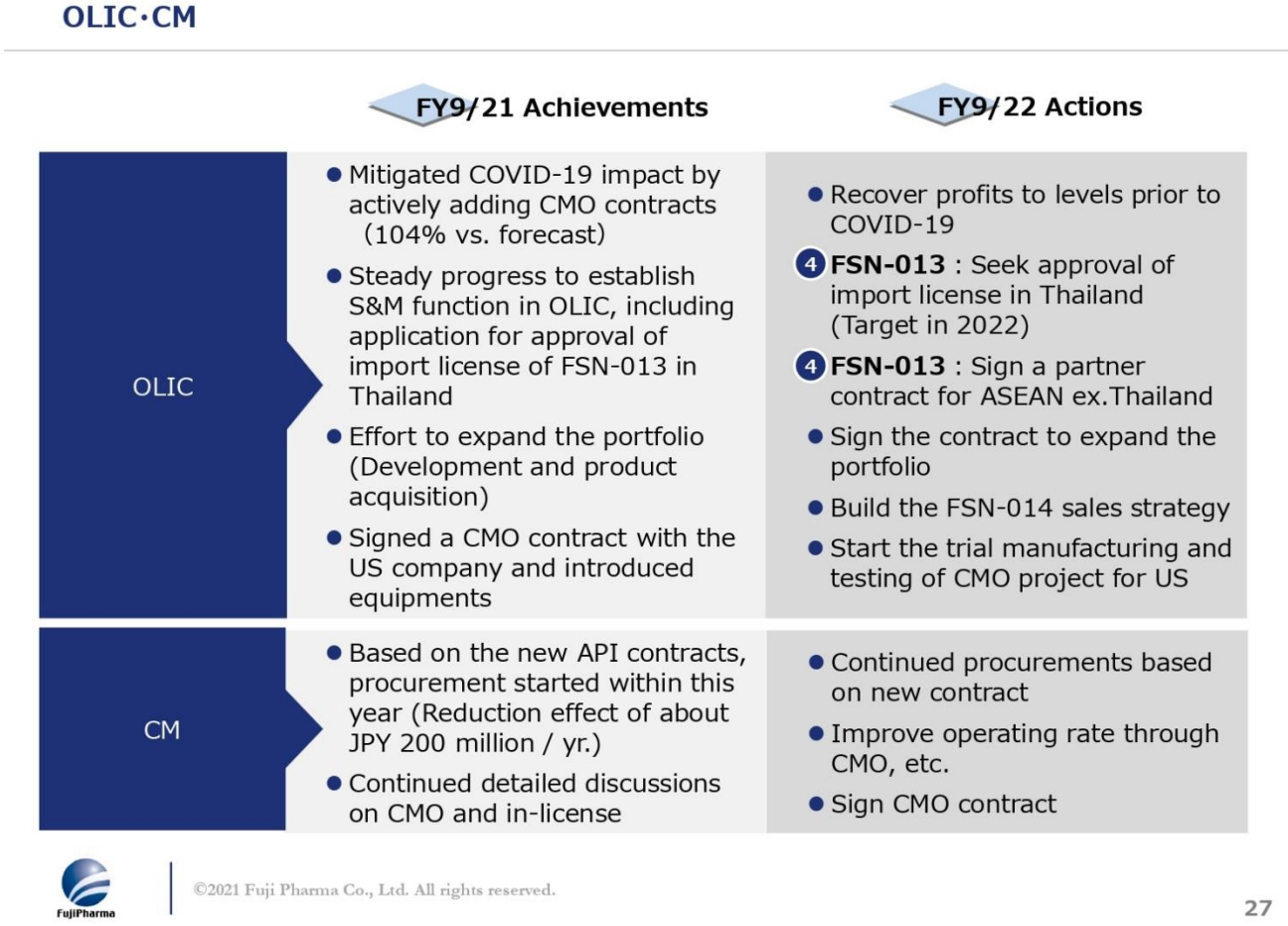
As previously reported, we are in an advanced stage of negotiations with Alvotech, a biosimilar development and manufacturing company in Iceland, regarding the commercialization of biosimilars in Japan.

We have selected a promising product for the Japanese market from the pipeline of Alvotech and are currently developing it. We are planning to apply for approval for 1 product this fiscal year. In addition, we have already agreed on the development of 4 products, and are currently negotiating for 2 more products.

We would like to firmly build up these pipelines and proceed with the application for approval toward the next Mid-term Business Plan.

In addition, in anticipation of the future production of biosimilars as I mentioned, we have already started preparing a multi-syringe line in Toyama.

We will explain more about the development status with Alvotech in Chapter 4.

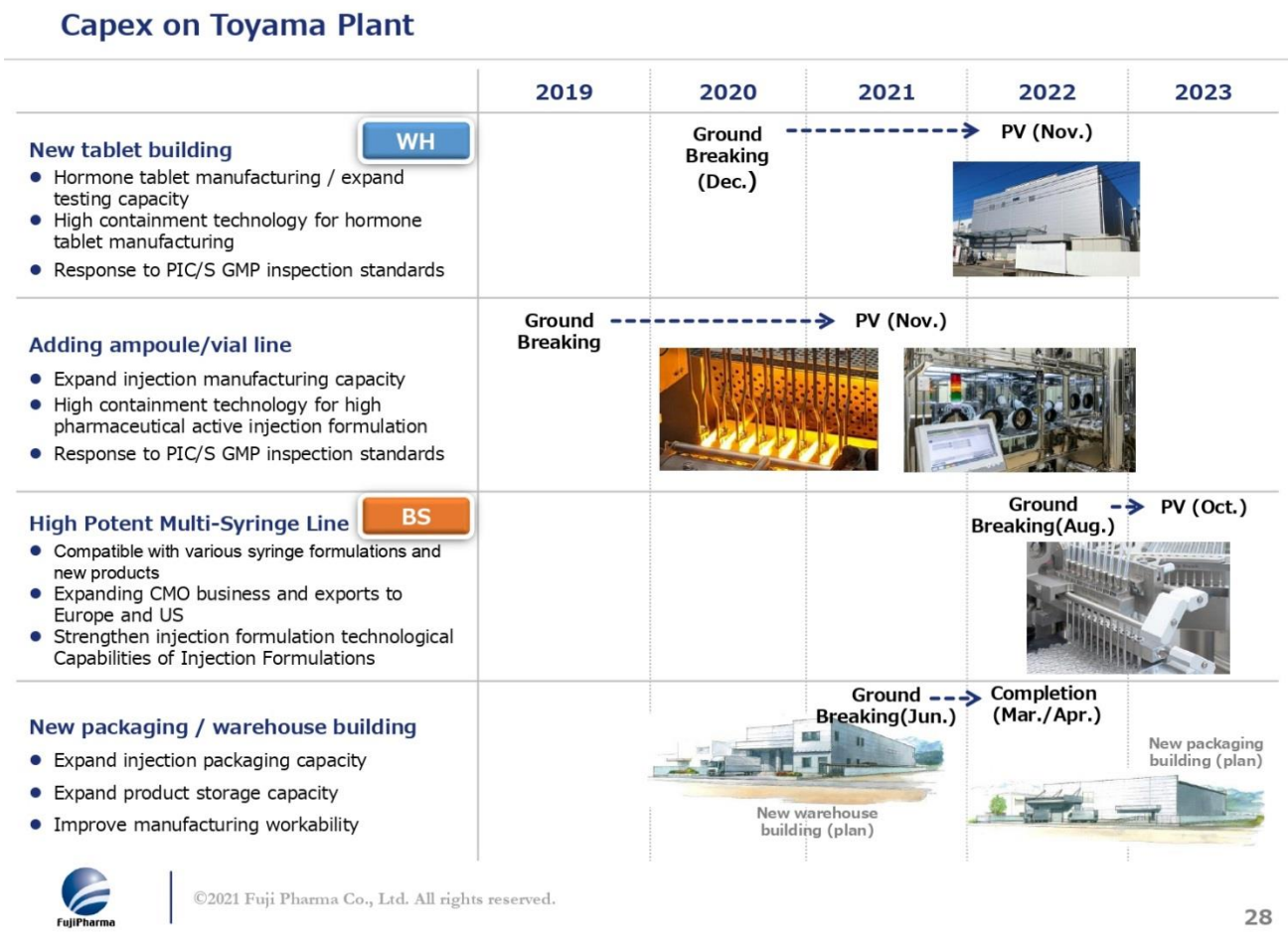


Next, OLIC and contrast media.

As I mentioned earlier, OLIC's CMO business is gradually recovering from COVID-19 impact. In addition, in the CMO fields, which is OLIC's core business, we have already started the trial manufacturing and testing of CMO business for US. We would like to finish firmly these things so that we can transform our business into a more globalized CMO business.

In addition, as I mentioned earlier, we applied for approval of FSN-013 in Thailand. This will be the core of OLIC's commercialization. We will explain the status of these applications individually later.

Lastly, in contrast media, we have decided to make a major change in the procurement of API from this fiscal year. By doing so, we will be able to reduce costs and ensure a more stable supply system than before. We are also planning to establish a sustainable contrast media business by firmly promoting new contract manufacturing.

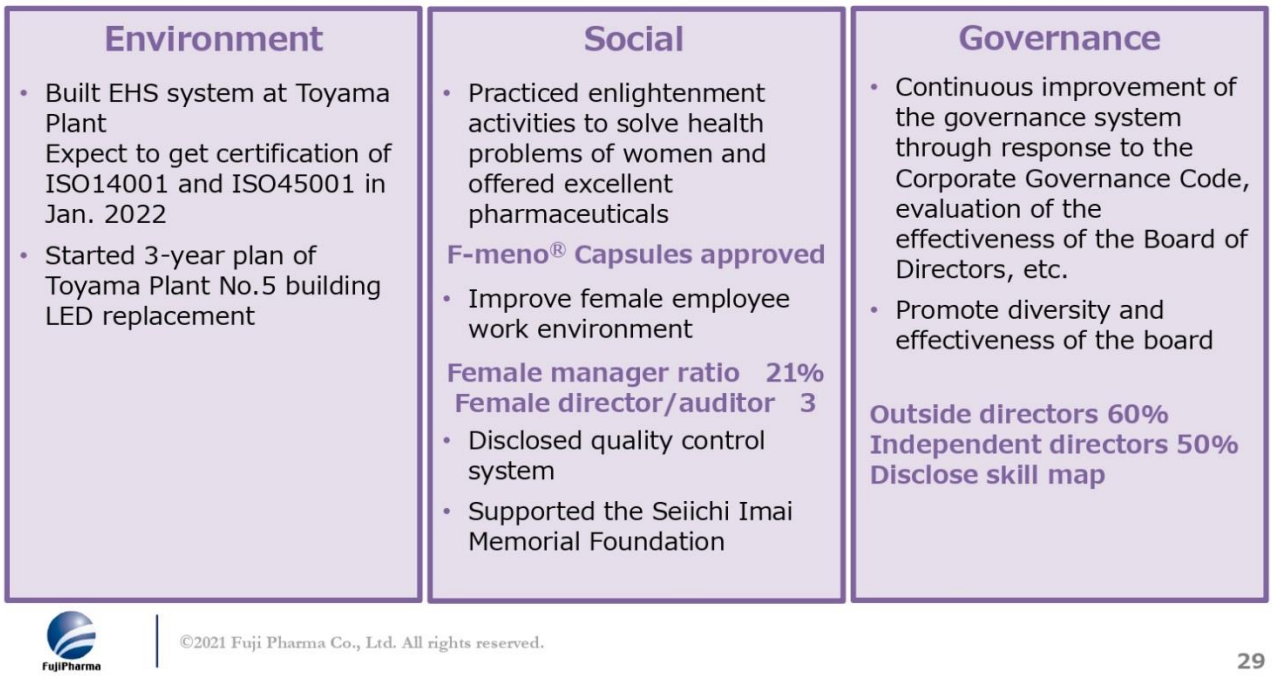


Now that I have discussed the 4 growth scenarios, I would like to talk a little about Capex that will support them.

As I have already explained in the 4 areas, the construction of the new tablet building, which will support the manufacture of 6 key women's healthcare products, is now progressing smoothly. We are planning to start operation in November next year. Our current manufacturing capacity is about 150 million tablets per year. After the completion of the new building, it will triple to 450 million tablets. We hope to fulfill our responsibility to ensure a stable supply.

We have also completed the installation of a new ampoule/vial line due to the aging of the current ampoule/vial line. We are now in the process of installing a new syringe line to manufacture biosimilars. This will be a pillar of our next Mid-term Business Plan, as mentioned earlier.

Last but not least, we have started construction of a second plant in Toyama to reinforce our packaging and distribution facilities. It will be completed and operational next year. We will let you know as soon as it is operational.



Next, a few words about sustainability.

Without the sustainable growth of society, our company will not be able to grow. It is becoming more and more important than ever to be trusted as a sustainable company by stakeholders in Japan and overseas. We will make steady progress in these areas: consideration for the environment, securing diverse human resources, and contributing to diverse lifestyles.

As you can see here, the female managers ratio is currently 21%, an increase of about 4% in 1 year from 17% at the end of last fiscal year. We have also increased the number of female directors from 1 to 3 in order to incorporate diverse opinions.

In terms of governance, as you can see here, the outside directors ratio is 60%, and we will continue to strive to be a sustainable company by receiving diverse opinions.

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

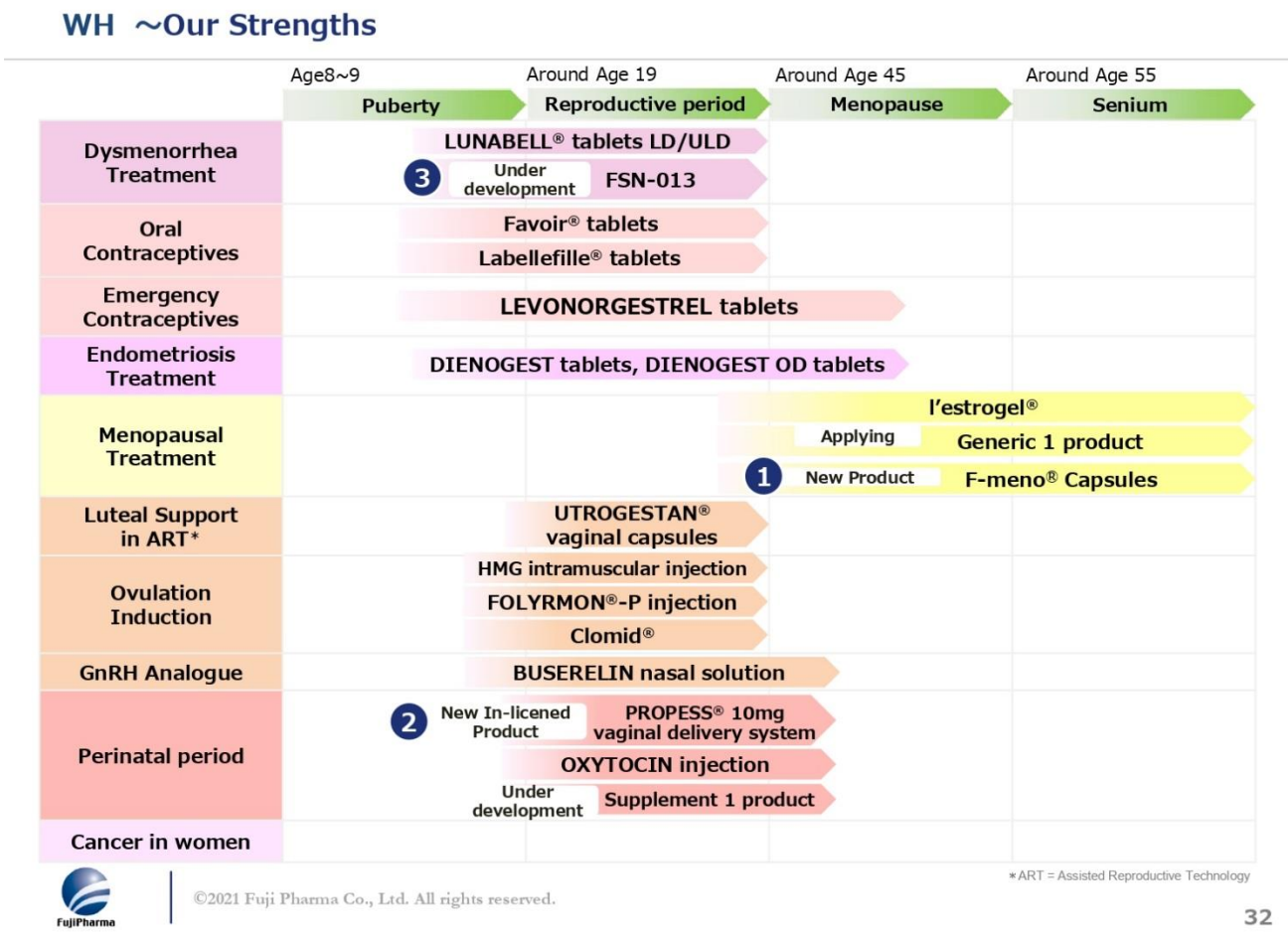
This will be the last slide in Chapter 3. This is about our quality control initiatives.

Please see the Quality Policy in the upper left corner. Our Board of Directors approved this newly established Quality Policy at its meeting in July this year. This quality policy was created based on our corporate philosophy of “We help people lead healthy lives by offering excellent pharmaceuticals.” We have established this Quality Policy in order to continue to provide high quality pharmaceutical products that can be used with confidence by patients, medical institutions, and society in general.

In the future, we will continue to comply with laws and regulations, ensure high quality, and guarantee reliability.

This concludes the explanation of Chapter 3, Progress of Mid-term Business Plan.

In Chapter 4, Mr. Mitsuhashi and Mr. Naganawa will explain about new drugs and biosimilars, respectively.



Mitsuhashi: Thank you. I would like to share with you some of the enhancements we have made to our product portfolio.

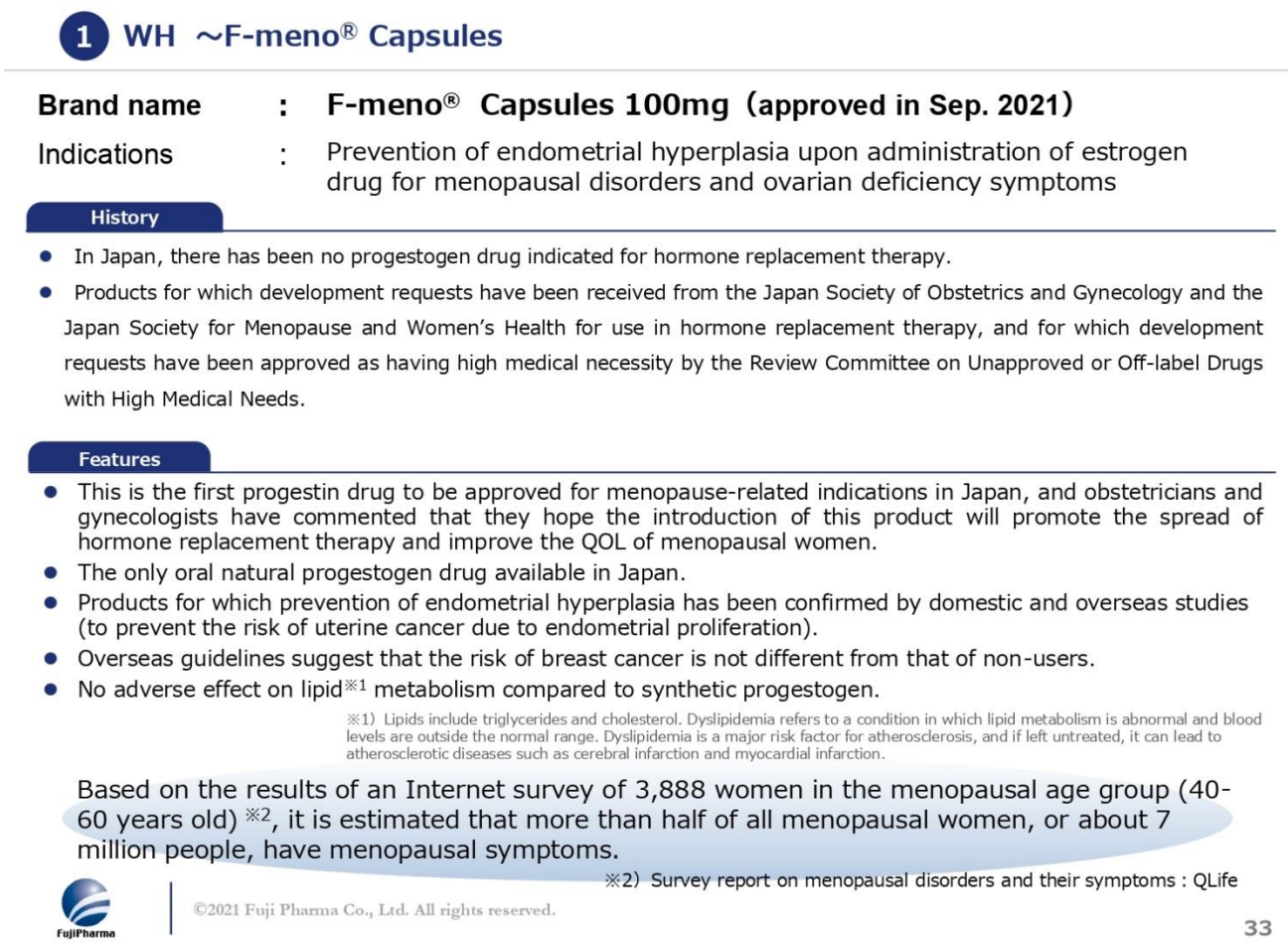
This table shows our main products in the women's healthcare field.

We are building a comprehensive product pipeline for women's diseases while adapting to individual life stages.

This time, F-meno® Capsules are essential to strengthen the menopausal area and PROPESS® is essential to strengthen the perinatal period. In the current fiscal year, we plan to launch a generic drug for menopausal disorders. Regarding perinatal period, we plan to launch a supplement for recommendation by medical professionals.

In order to expand our contribution to well-being of women, we will also strengthen our products related to cancers in women, such as breast, ovarian and cervical cancer.

With regard to diseases specific to women, the market continues to expand for many diseases such as dysmenorrhea, endometriosis, infertility, and menopausal disorders. We will continue to develop and provide excellent drugs to meet these needs.



Naganawa: I'm Naganawa from Research and Development Division. I will explain to you about F-meno® Capsules.

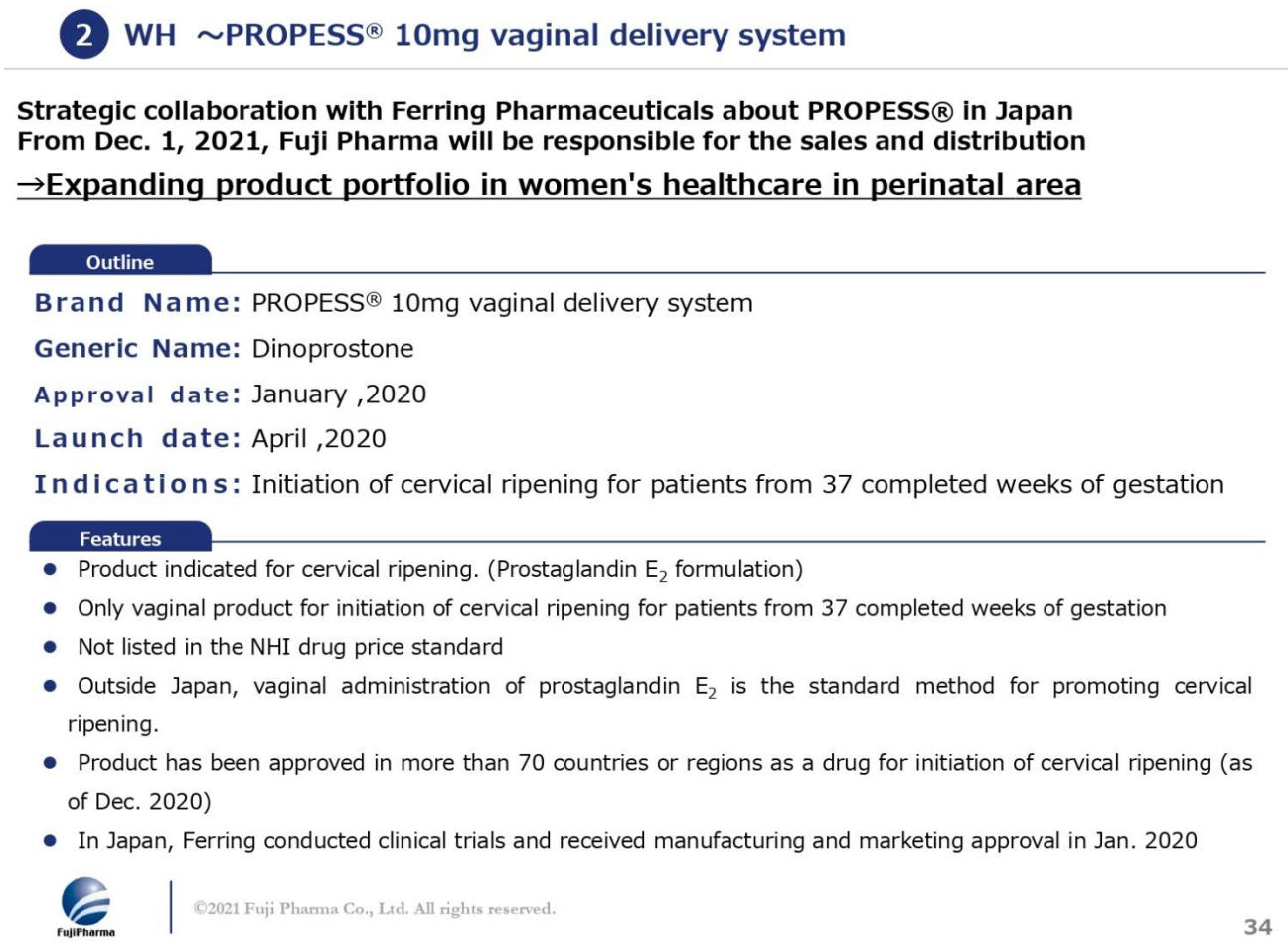
F-meno® Capsules were developed in response to a request from Japan Society of Obstetrics and Gynecology and Japan Society for Menopause and Women's Health for the development of a progestin drug for the indication of hormone replacement therapy. The application was submitted in December last year, and after a 10-month review period, we received approval in September this year. The product will be available after the NHI drug price listing. It is scheduled to be launched within this year.

As the first progestin drug with a menopause-related indication in Japan, 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 features of this product are the following reasons. First, it is the only oral natural progesterone drug available in Japan. Secondly, it is the product for which prevention of endometrial hyperpiesia confirmed by domestic and overseas studies. Thirdly, Overseas guidelines suggest that the risk of breast cancer is not different from that of non-users. Fourthly, no adverse effect on lipid※1 metabolism compared to synthetic progestogen.

As a result of a survey of 3,888 women in the menopausal age group, it was estimated that approximately 7 million people (half of the female population in the menopausal age group) have menopausal symptoms. We believe that F-meno® Capsules can contribute to improving the quality of life of menopausal age group.

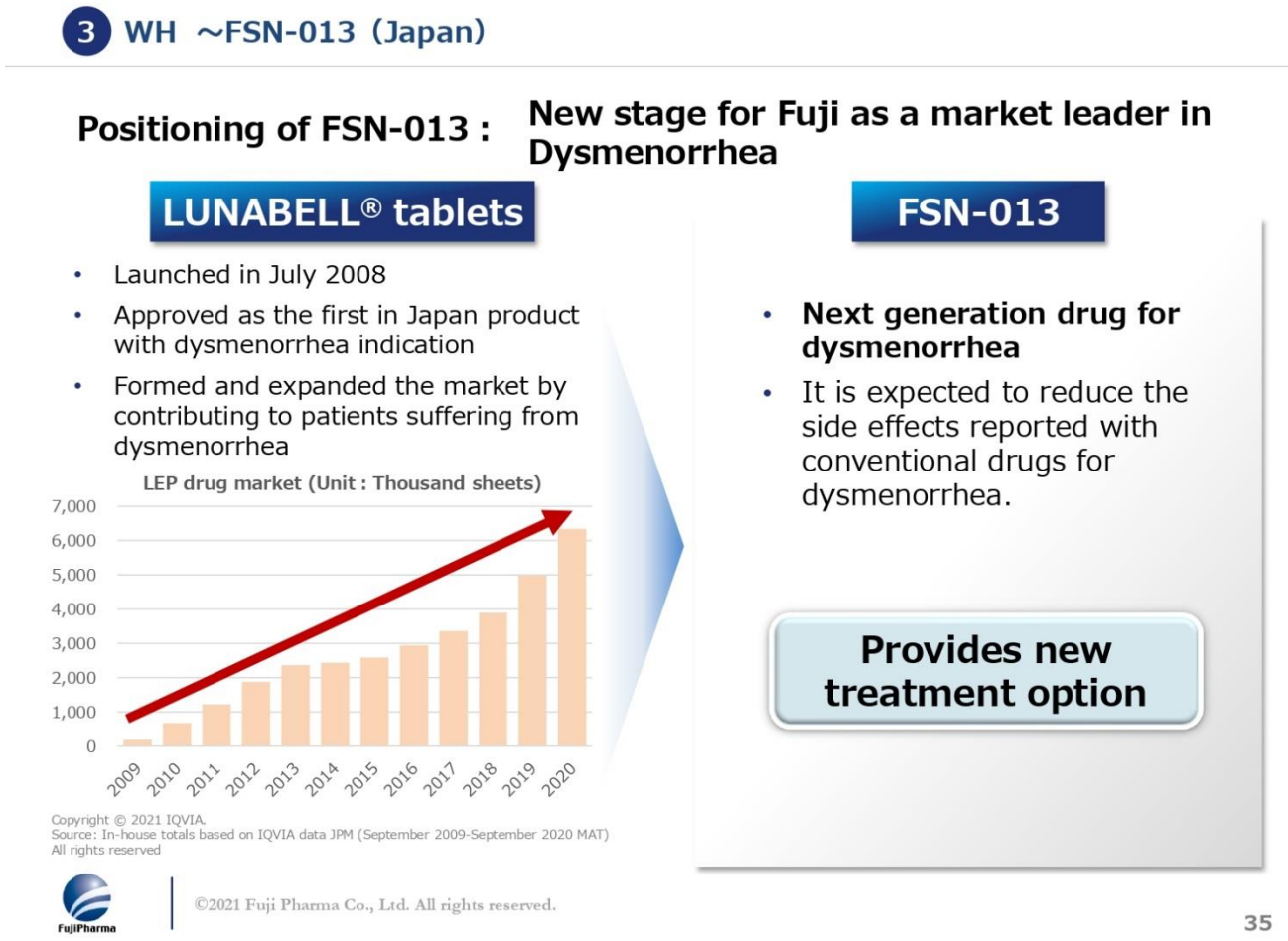
Next, please.



Mitsuhashi: The product indicated for cervical ripening PROPESS® was approved for manufacturing and marketing in Japan by Ferring Pharmaceuticals in January 2020. It has been on the market since April of that year.

PROPESS® is the only vaginal product for initiation of cervical ripening for patients from 37 completed weeks of gestation. Since its approval in US in 1995, it has been approved in more than 70 countries or regions as a drug for initiation of cervical ripening. We, with its strength in obstetrics and gynecology, will be responsible sales and distribution from December 1. We will provide information to approximately 2,000 perinatal facilities in Japan, which Ferring Pharmaceuticals was unable to cover. We will work together with medical professionals in Japan to firmly promote the use of drugs that are standard overseas.

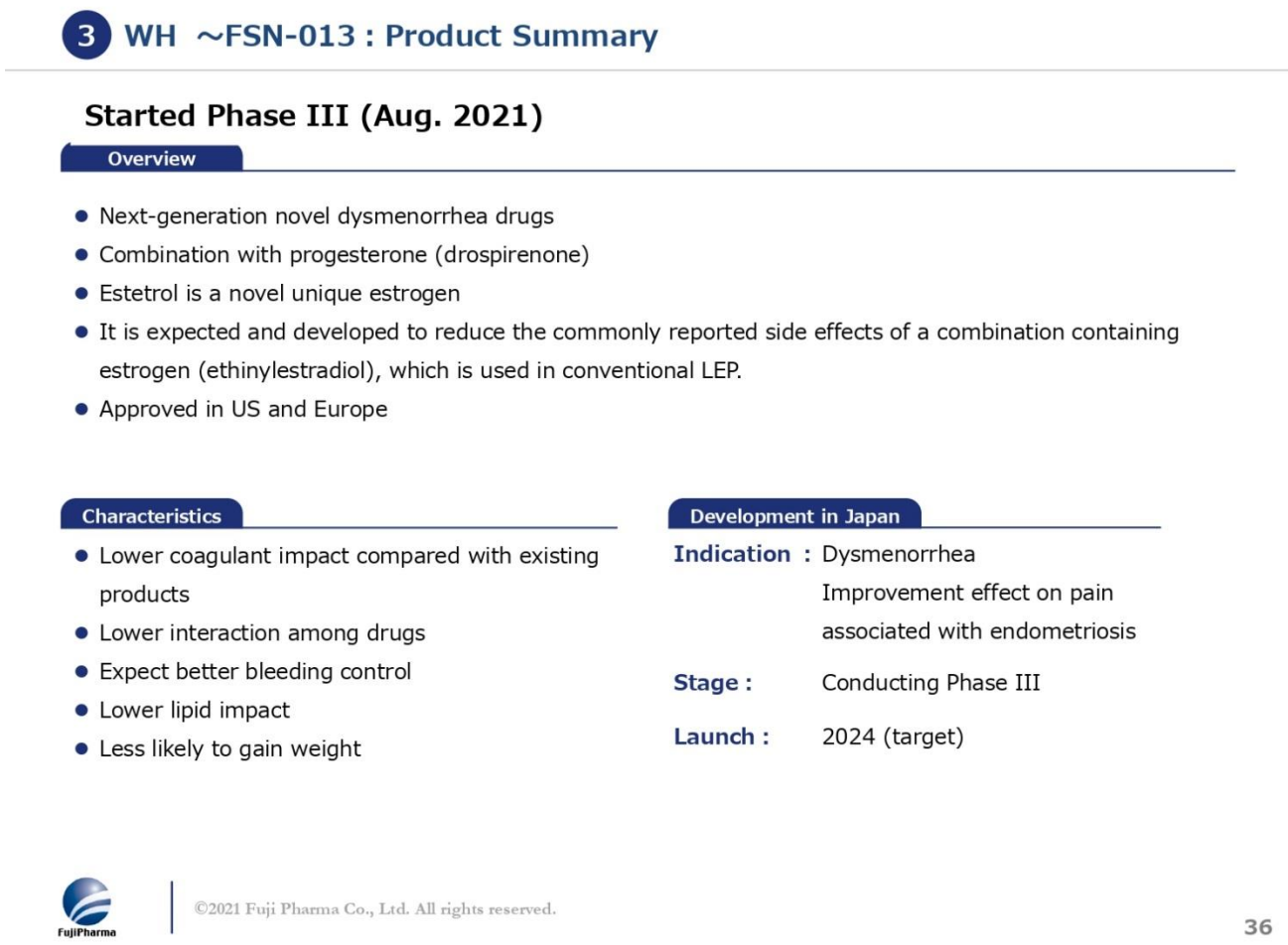
We have been dealing with several drugs relating to the perinatal area, and will continue to further strengthen our presence in this area in the future.



We have created a new market for the treatment of dysmenorrhea with LUNABELL® tablets.

FSN-013, which is currently under development, is positioned as a next-generation dysmenorrhea treatment drugs and is being developed with the aim of providing a new treatment option.

Sales in this segment have been declining due to the impact of generics following the expiration of the patent for LUNABELL® tablets. However, we will work to expand our market share again with this product.



Naganawa: Next, I would like to discuss the current development status.

Since Phase II trials showed promising results, we started Phase III trials in August 2021.

FSN-013, developed as a next-generation dysmenorrhea treatment drugs, is a combination of natural estrogen with a new and unique action and drospirenone. This is called estetrol. In US and Europe, it has already been approved and launched as an oral contraceptive. In Japan, development is underway for dysmenorrhea and the improvement effect on pain associated with endometriosis.

It is expected to reduce the commonly reported side effects of a combination containing estrogen (ethinylestradiol), which is used in conventional LEP.

Estetrol is lower coagulant impact compared with existing products, lower interaction among drugs due to no specificity of metabolizing enzymes in the liver, expected better bleeding control, lower lipid impact, and less likely to gain weight.

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	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. 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.
Evaluation items	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) Secondary endpoint : Evaluation scale of pain for dysmenorrhea (VAS) Change from baseline observation phase, etc. Safety endpoint : Incidence of adverse events and adverse drug reactions

Next, I will briefly explain about Phase III trials.

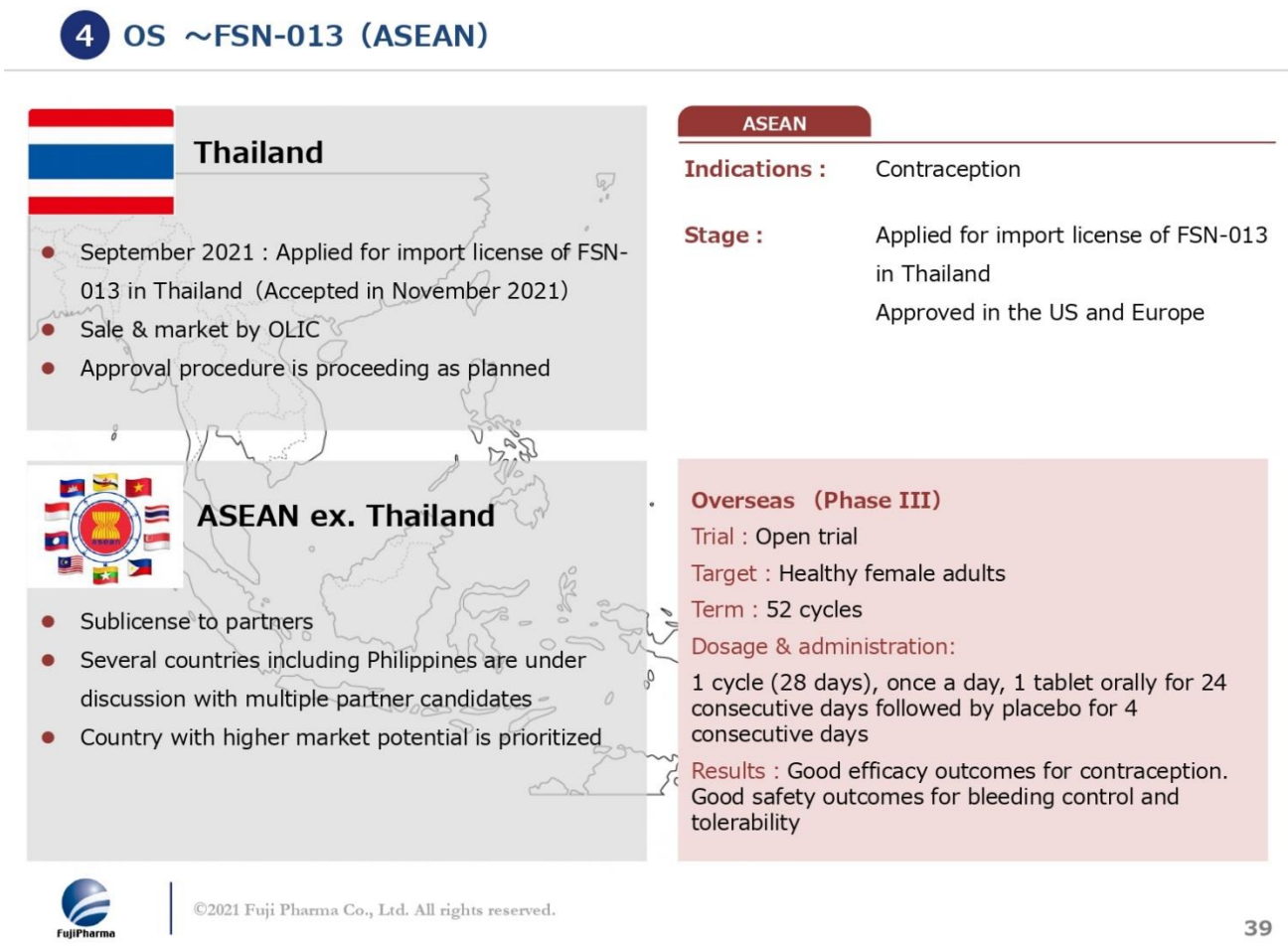
As for Phase III trials, we are conducting 2 trials for each indication. The study shown here is a double-blind, placebo-controlled trial in patients with dysmenorrhea. The target number of cases is 150, and the study is designed to evaluate the efficacy and safety of the drug for dysmenorrhea based on the change in the total dysmenorrhea score from before treatment.

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	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. 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.
Evaluation items	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). Secondary endpoints: Pelvic pain (lower abdominal and lower back pain) during menstrual or withdrawal bleeding, etc. Safety endpoints: Incidence of adverse events and adverse drug reactions

38

This study is a double-blind, placebo-controlled trial in patients with endometriosis. This is a study to verify the improvement, efficacy and safety of the effect of pain for endometriosis by the amount of VAS change in the most severe pelvic pain, such as lower abdominal pain and back pain, from before administration. Both trials started in August and are currently progressing as planned.



Mitsuhashi: FSN-013 is also being prepared for lounch in ASEAN.

In Thailand, an application for import approval was submitted to the Thailand FDA in September. We will continue with setting up a sales organization and building relationships with physicians. We are aiming to develop a base for sales by the time of anticipated approval within the next fiscal year.

In ASEAN countries other than Thailand, we expect to license out the product and outsource approval and sales to partner companies. We are negotiating specific contracts with several companies in several countries in addition to the Philippines.

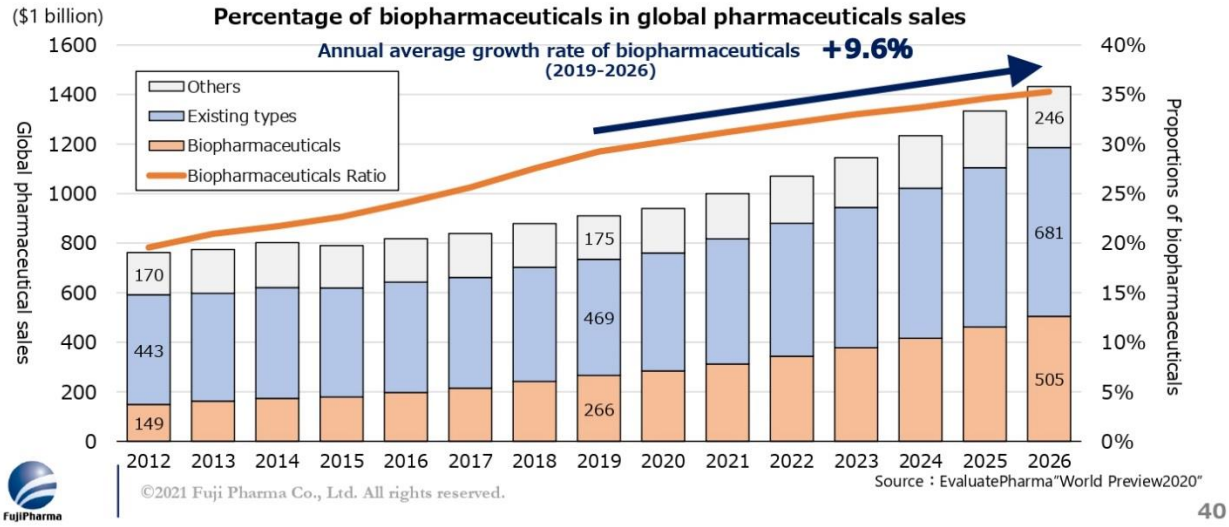
5 BS ～Market and strategy

■ 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.



40

Next, I would like to report on our biosimilar initiatives.

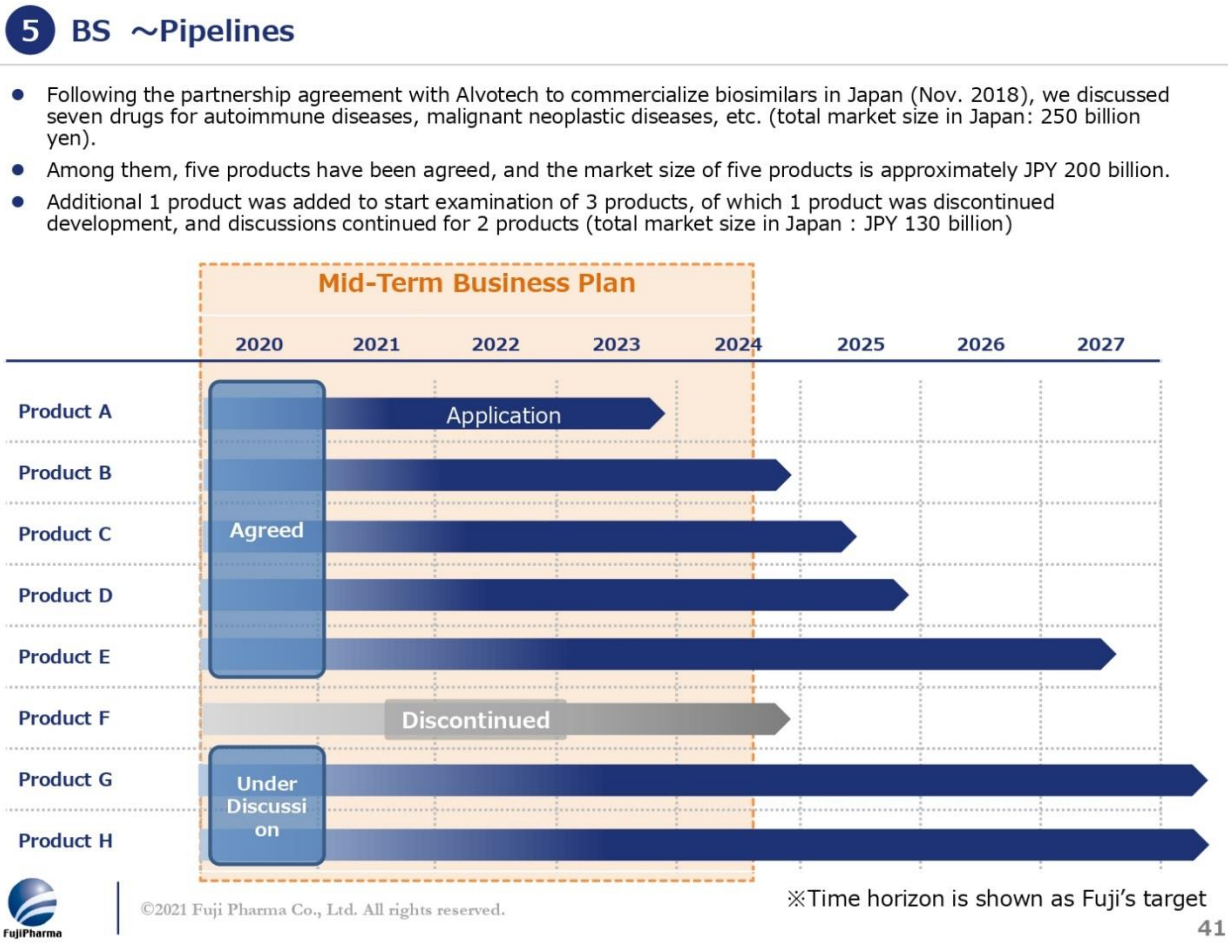
As you know, the percentage of pharmaceutical sales accounted for by biopharmaceuticals continues to grow significantly. As expectations regarding the widespread use of biosimilars are rising, we will work on a number of biosimilars in our product portfolio to contribute to reducing the burden on patients and curbing medical costs.

Although there are significant barriers to entry in the biosimilars market, our alliance with Alvotech allows us to negotiate on a preferential basis for the development of products in Japan from their many development pipelines.

In addition, Alvotech has sales partners in each of the overseas areas, and their supply volume is larger, making them more cost responsive.

In addition, we are planning to obtain approval not only for overseas manufacturing, but also for manufacturing at the new high-potency multi-syringe line to be introduced at the Toyama Plant. This will ensure a stable supply.

In the biosimilars business, we will develop our business on the strength of our abundant pipeline, cost responsiveness, and stable supply.



Next, our specific product portfolio.

We have already reached agreements with Alvotech for 5 products and are moving forward with development.

As for the development status, we plan to apply for approval for 1 product in Japan during this fiscal year.

We are also pleased to announce that we are in discussions with Alvotech regarding 2 new products with a total domestic market size of approximately JPY130 billion.

We are in discussions with partners other than Alvotech regarding biosimilars, and will continue to expand our biosimilar portfolio.

That concludes my presentation.

Moderator: Thank you very much.

Question & Answer

Moderator: We will now move on to the question-and-answer session.

Please feel free to ask any questions you may have in the chat room.

I will now read the first question. It is as follows.

"What is the status of the partnership with M3 relating to FSN-013?"

Iwai: I will take this question.

First of all, we have concluded a joint development agreement with M3 for FSN-013. Based on this joint development agreement, we are now in the process of conducting regular progress meetings, visualizing the status of both companies.

In terms of sales, we are now in the process of examining the possibility of e-Promotion for F-meno® Capsules, which received approval in September.

We are currently discussing with M3 about how we can improve the efficiency of our sales and marketing activities for the approved product, while at the same time firmly advancing the development of FSN-013.

Thank you.

Moderator: Thank you very much.

I will move on to the next question.

"The oral contraceptives awareness campaign was mentioned, but are sales of oral contraceptives expected to grow this fiscal year as well?"

Iwai: I would like to reply to this question as well.

First of all, as shown in the presentation, this area is currently experiencing solid growth. As for the oral contraceptives market itself, at present, the penetration rate of oral contraceptives in Japan is less than 3%. As I mentioned at the briefing session in May, the usage rate in Europe and the US is about 30%. Compared to those countries, use in Japan is still quite low. We recognize that there is still room for growth in this area.

Growth has not been very large, but it has been steadily increasing every year. In order to further promote this growth, we would like to create an environment in which people can use drugs with peace of mind. To do this, we are working to provide people with correct information on drugs through educational activities.

As for the question of whether there will be growth in the future, we will continue our efforts to provide accurate information.

Thank you.

Moderator: Thank you very much.

I will move on to the next question.

"Please describe the effect of insurance coverage for infertility treatment on your Company."

Iwai: This is a difficult question to answer, but first of all, as a market, insurance coverage will allow more people to have access to infertility treatment. In this sense, we believe that we will be able to contribute to the expansion of this field.

On the other hand, the authorities have not made any decision on the issue of insurance coverage yet, so we have not yet been able to estimate how much of an impact it will have. However, as I mentioned, we hope to contribute to patients suffering from infertility with our treatment options.

Moderator: Thank you very much.

Now, I would like to introduce the next question.

"Sales of the 2 generic contrast media have been decreasing year by year. Please tell us about the sales forecast for the fiscal year ending September 2022 and the future of the contrast media business."

Iwai: I would like to take this question as well.

As for the sales of generic contrast media for the fiscal year ending September 30, 2022, IOPAMIDOL sales are expected to decrease by approximately JPY400 million from the previous fiscal year. IOHEXOL sales are expected to decrease by approximately JPY380 million from the previous fiscal year.

However, as I mentioned in my presentation, we are committed to making our contrast media business sustainable by reducing costs through new raw material procurement and other measures. Contract manufacturing will also contribute. Our efforts to make our contrast media business sustainable through cost reductions in new raw material procurement and contract manufacturing remain unchanged. With this type of contract manufacturing and product sales, we intend to maintain the sustainability of this business area.

Moderator: Thank you very much.

Now, I would like to introduce the next question.

"What is the marketability of oral contraceptives in Thailand?"

Iwai: I will pass this question to Mr. Mitsuhashi.

Mitsuhashi: This is Mitsuhashi. Please allow me to answer.

According to a United Nations survey, the penetration of oral contraceptives in Thailand is just under 20%, and their use is increasing. The oral contraceptives market in Thailand is broadly classified into 3 categories based on price range.

We are targeting the premium price range, and growth in this premium price range has been more significant than in other price ranges.

By launching the next-generation FSN-013, which contains a new active ingredient estetrol that is expected to reduce side effects, we will provide a new treatment option for patients.

Thank you.

Moderator: Thank you very much.

Now, I would like to introduce the next question.

"What is the value of OLIC's new contracted projects for the US in terms of OLIC's CMO business?"

Iwai: This is a really new initiative. As you all know, the hurdles to getting approval in the US are quite high.

We believe that overcoming these challenges and winning the contract business will prove that we are able to meet stricter manufacturing standards, which will greatly increase OLIC's credibility and trust in the CMO business in Asia.

At the moment, a large part of our business is outsourced within Thailand, but we are aiming to expand this business to Asia, Europe, and the United States. This is a very meaningful first step.

This is a good opportunity for us to expand our business in the US.

Thank you.

Moderator: Thank you very much.

Now, I would like to introduce the next question.

"In Japan, the treatment of menopausal disorders does not seem to have progressed much. In this area, what kind of efforts will Fuji Pharma make in the future?"

Iwai: I think this was covered to some degree in the portfolio section, so I would like to pass this question to Mr. Mitsuhashi.

Mitsuhashi: This is Mitsuhashi. Thank you.

Estrogen and progestin are used in hormone replacement therapy for menopausal disorders. We have an estrogen preparation, L'estrogel, and a generic drug that is under regulatory review. We also have a progestin preparation, F-meno® Capsules, and we will work toward hormone replacement therapy for menopausal disorders with these 2 products.

In addition to hormone replacement therapy, we are also working on high value-added supplements for recommendation by medical professionals, and plan to contribute to the improvement of women's well-being.

Thank you.

Moderator: Thank you very much.

Now, I would like to introduce the next question.

The development of supplements in the field of women's healthcare was presented in May. What is the status of development at present?"

Iwai: Mr. Mitsuhashi will take this question as well.

Mitsuhashi: This is Mitsuhashi.

As planned, we are planning to sell medical professional-recommended supplements for the perinatal phase during this fiscal year.

Thank you.

Moderator: Thank you very much.

Now, I would like to introduce the next question.

"You mentioned that you are planning to build a system to manufacture biosimilars either overseas or in Japan, but will you also build a culture facility in Japan?"

Iwai: I would like to respond to this question.

We have no plans for a culture facility. As I mentioned in my explanation, Alvotech is in charge of the development and manufacturing of the drug. We are planning to bring the drug substance manufactured by Alvotech using their culture facilities to Japan for formulation in Japan.

We are currently preparing the equipment for this purpose, which I mentioned in my presentation as a multi-syringe line. We are preparing for the actual introduction of the equipment in this fiscal year.

That's all.

Moderator: Thank you very much.

The next question will be the last one as we are approaching the end of the session. The next question is as follows.

"This fiscal year marks the third year of your Company's Mid-term Business Plan. "It seems that there may still be a little way to go to the goals of JPY50 billion in sales and JPY5 billion in operating profit. How confident are you about achieving these goals?"

Iwai: As I explained when the plan was announced, during the first 5 years of the Five-Year Medium-Term Management Plan, we are currently aiming to increase both sales and profits. We have seen some degree of increase.

We will expand our portfolio through a combination of product development, which we are currently preparing, and expansion of sales of existing products. By firmly advancing this portfolio expansion, we are currently working to achieve the JPY50 billion target for the fiscal year ending September 30, 2024 as originally forecast.

Thank you.

Moderator: Thank you very much.

We have received many questions, and we apologize for not being able to answer all of them. If you have any questions after the briefing, please contact the Corporate Planning Department as indicated in the briefing materials.

This concludes the financial results briefing for the fiscal year ending September 30, 2021 for Fuji Pharma.

Thank you to everyone for joining us.

[END]

Document Notes

1. *Portions of the document where the audio is unclear are marked with [Inaudible].*
2. *Portions of the document where the audio is obscured by technical difficulty are marked with [TD].*
3. *This document has been translated by SCRIPTS Asia.*

Disclaimer

SCRIPTS Asia reserves the right to edit or modify, at its sole discretion and at any time, the contents of this document and any related materials, and in such case SCRIPTS Asia shall have no obligation to provide notification of such edits or modifications to any party. This event transcript is based on sources SCRIPTS Asia believes to be reliable, but the accuracy of this transcript is not guaranteed by us and this transcript does not purport to be a complete or error-free statement or summary of the available data. Accordingly, SCRIPTS Asia does not warrant, endorse or guarantee the completeness, accuracy, integrity, or timeliness of the information contained in this event transcript. This event transcript is published solely for information purposes, and is not to be construed as financial or other advice or as an offer to sell or the solicitation of an offer to buy any security in any jurisdiction where such an offer or solicitation would be illegal.

In the public meetings and conference calls upon which SCRIPTS Asia's event transcripts are based, companies may make projections or other forward-looking statements regarding a variety of matters. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the applicable company's most recent public securities filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are accurate and reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the anticipated outcome described in any forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT TRANSCRIPTS IS A TEXTUAL REPRESENTATION OF THE APPLICABLE PUBLIC MEETING OR CONFERENCE CALL. ALTHOUGH SCRIPTS ASIA ENDEAVORS TO PROVIDE ACCURATE TRANSCRIPTIONS, THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE TRANSCRIPTIONS. IN NO WAY DOES SCRIPTS ASIA OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BY ANY PARTY BASED UPON ANY EVENT TRANSCRIPT OR OTHER CONTENT PROVIDED BY SCRIPTS ASIA. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S PUBLIC SECURITIES FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS. THIS EVENT TRANSCRIPT IS PROVIDED ON AN "AS IS" BASIS. SCRIPTS ASIA DISCLAIMS ANY AND ALL EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE, FREEDOM FROM BUGS, SOFTWARE ERRORS OR DEFECTS, AND ACCURACY, COMPLETENESS, AND NON-INFRINGEMENT.

The content of this document may be edited or revised by SCRIPTS Asia at any time without notice.