Fuji Pharma Co., Ltd.

Q2 Financial Results Briefing for the Fiscal Year Ending September 2021

May 20, 2021

Event Summary

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[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 joining us today for Fuji Pharmaceutical Industry's financial results briefing for the first half of the fiscal year ending September 30, 2021. First of all, I would like to introduce today's attendees.

Takayuki Iwai, President and CEO.

Iwai: Thank you very much.

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

Mitsuhashi: Thank you very much.

Moderator: Masayuki Naganawa, Corporate Officer, Vice General Manager of Research & Development Division.

Naganawa: Thank you very much.

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

Sato: Thank you very much.

Moderator: In the first part of the presentation, Mr. Iwai and Mr. Sato will provide an overview of the consolidated financial results for the second quarter of the fiscal year ending September 30, 2021, as well as the progress of Mid-term Business Plan. In the second part, Mr. Iwai, Mr. Mitsuhashi, and Mr. Naganawa will talk about the new drug development pipeline.

We will then proceed to the Q&A session. We would like to take as many questions as time permits, so please feel free to send us your questions. If you have any questions, please feel free to send us a message at any time, even during the explanation.

We also ask for your cooperation in completing the questionnaire so that we can use it as a reference for future IR activities. We will explain how to answer the questions at the end of the briefing session, so please wait until the end.

I would now like to move on to the first part of the presentation. Thank you very much, Mr. Iwai.

Iwai: Thank you for taking time out of your busy schedule to join us today for Fuji Pharmaceutical's financial results briefing for the second quarter of the fiscal year ending September 30, 2021. Due to the current coronavirus pandemic, we have decided to hold this session in a web format. Thank you.

Today, as the moderator has already mentioned, the first part will be a summary of the second quarter financial results and the progress of Mid-term Business Plan. The second part, regarding the status of our efforts in the area of women’s healthcare, will focus on environmental aspects and the status of the development pipeline.

First, Mr. Sato will provide an overview of the consolidated financial results for the second quarter of the fiscal year ending September 30, 2021.

Sato: Hello. Thank you. First of all, I would like to provide an overview of our financial results for the first half of the fiscal year ending September 30, 2021. Please see the bottom right part of page 4.

To summarize the results for the second quarter, sales in the field of women's healthcare increased YoY by JPY370 million, or 2.2%. Steady sales in this field compensated for the impact of the coronavirus pandemic on contrast media and OLIC contract businesses. Expenses decreased YoY by JPY940 million, or 15.8%. This is due to a decrease in SG&A expenses resulting from the coronavirus pandemic, and the postponement of incurring some R&D expenses to the second half of the fiscal year. As a result, operating income increased by JPY950 million, or 54.8%, from the previous fiscal year.

In R&D, we filed for approval of FSN-011-01 in December 2020. In addition, Mayne Pharma, the U.S. licensee of FSN-013, received FDA approval for the drug in April.

Summary of FY9/21 2Q Consolidated Financial Results

- Net Sales : Increased by JPY 372 million (YoY +2.2%) due to steady sales of women's healthcare major products, despite COVID-19 impact
- Operating Profit : Increased by JPY 951 million (YoY +54.8%) due to delay in R&D expenses to the second half and decrease in SG & A expenses due to COVID-19
- Net Profit : Increased by JPY 1,711 million (YoY +550.5%), since the impairment of investment securities in the previous fiscal year has disappeared

(¥million)	FY9/20 First half	**FY9/21 First half**	YoY Change Amount	YoY Change Ratio	**FY9/21 First half forecast**	vs Fcst Achievement Ratio	**FY9/21 Forecast**	vs Fcst Progress Ratio
Net Sales	16,905	**17,277**	372	2.2%	**17,301**	99.9%	**34,702**	49.8%
Gross Profit	7,650	**7,664**	14	0.2%	-	-	-	-
Gross Margin	45.3%	**44.4%**			-	-	-	-
SG&A Expenses	5,914	**4,977**	▲ 937	-15.8%	-	-	-	-
SG&A Margin	35.0%	**28.8%**			-	-	-	-
Operating Profit	1,735	**2,686**	951	54.8%	**1,685**	159.5%	**2,857**	94.0%
Operating Margin	10.3%	**15.5%**			**9.7%**		**8.2%**	
Ordinary Profit	1,610	**2,738**	1,128	70.0%	**1,659**	165.0%	**2,807**	97.5%
Ordinary Margin	9.5%	**15.8%**			**9.6%**		**8.1%**	
Profit Attributable to Owners of Parent	310	**2,021**	1,711	550.5%	**1,302**	155.3%	**2,100**	96.2%
Profit Margin	1.8%	**11.7%**			**7.5%**		**6.1%**	
Capital Expenditure	1,682	**1,567**	▲ 115	-6.8%			**6,672**	23.5%
Depretiation (Including Leased Equipment)	908	**1,015**	107	11.7%			**1,581**	64.2%
R&D Expenses	1,586	**861**	▲ 725	-45.7%			**3,200**	26.9%
R&D Expenses Ratio	9.4%	**5.0%**					**9.2%**	

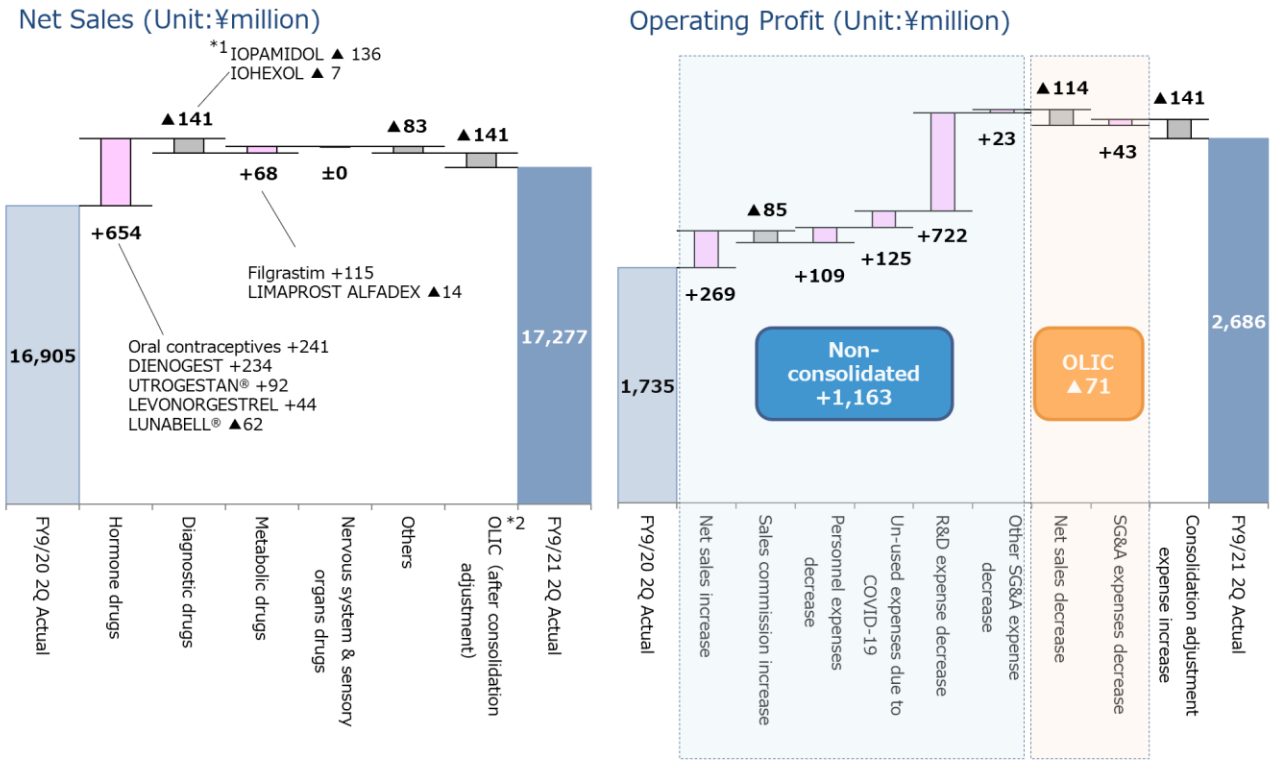
Next page. I will talk about the 3 points here: gross profit margin, capital investment, and research and development expenses.

Regarding the gross profit margin, growth in the women's healthcare field and a decrease in contrast media sales has resulted in an improvement in product mix. However, the impact of the NHI price revision in April 2020 and the increase in product disposal compared to the previous fiscal year resulted in a decrease of 0.9%.

In terms of capital investment, we are making progress almost as planned, mainly with the construction of a new formulation building at the Toyama Plant.

Finally, research and development expenses are expected to be almost in line with the plan for the full year, although there has been a large decrease due to the fact that items planned for the first half of the fiscal year have been moved to the second half.

Summary of FY9/21 2Q Consolidated Financial Results (YoY)



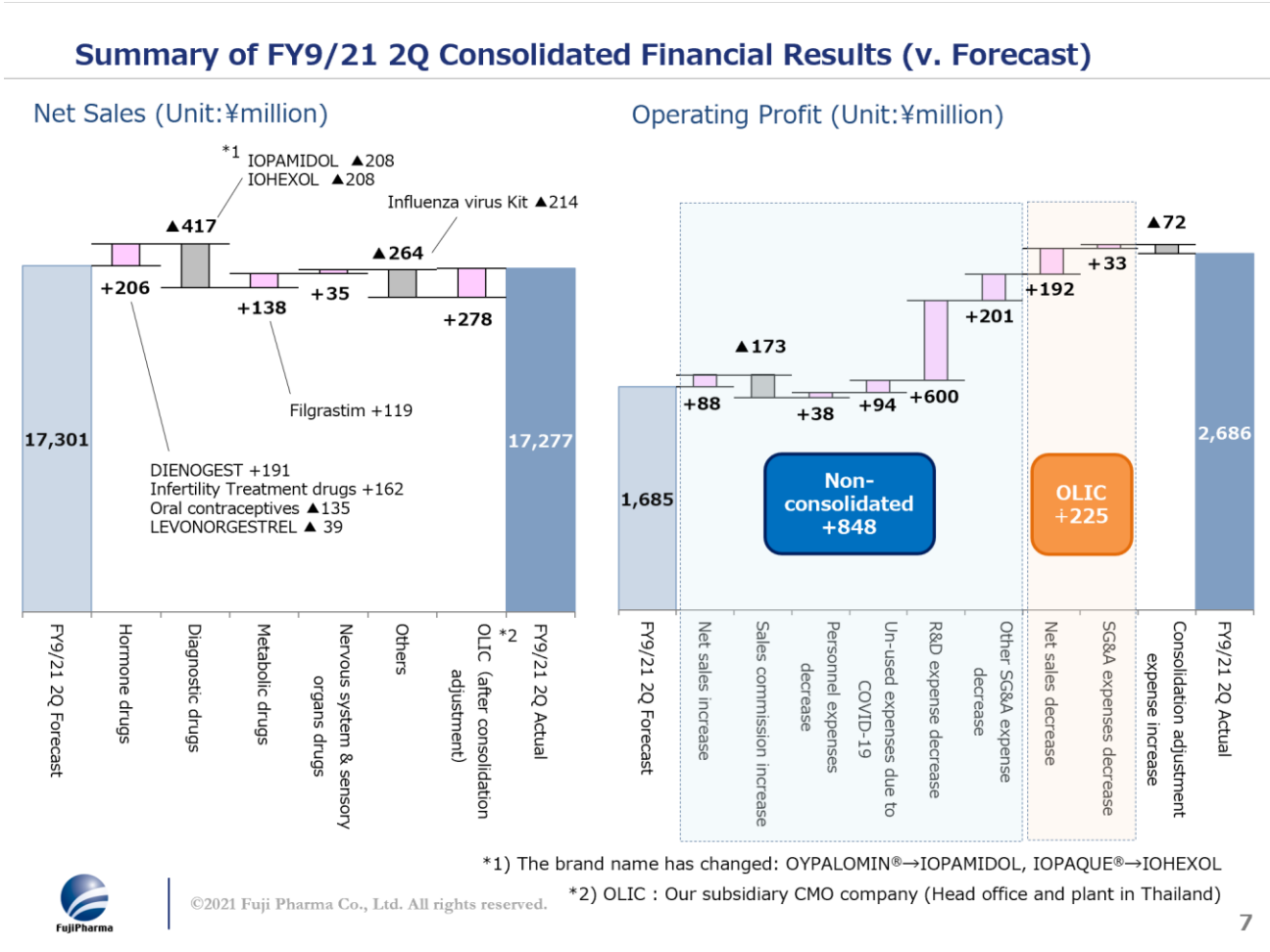
*1) The brand name has changed: OYPALOMIN®→IOPAMIDOL, IOPAQUE®→IOHEXOL

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

Next page. This is a reanalysis of the first half of the year compared to the previous period.

Please see the chart on the left for sales. As I mentioned in the highlights, hormone products in the field of women's healthcare grew significantly, while sales of contrast media and OLIC decreased due to the impact of the coronavirus pandemic. Overall, despite the impact of the NHI drug price revision in April 2020, we were able to achieve a YoY increase in sales.

Please see the chart on the right for operating income. The decrease in performance-linked compensation resulted in an increase in personnel expenses of approximately JPY100 million. Coronavirus-related reductions in expenses amounted to approximately JPY100 million, and the postponement of R&D expenses contributed approximately JPY700 million.



This is a reanalysis compared to the initial forecast.

Net sales are shown in the chart on the left. We had planned to increase sales of contrast media through sales activities even during the coronavirus pandemic, but its prolonged impact has had a negative impact on results.

In addition, there was a decrease in revenue due to this year's reduced number of influenza cases, partly as a result of anti-coronavirus measures. The decline in sales was limited to a slight decrease compared to the forecast due to strong performance in the area of women's healthcare and a one-time revenue buildup at OLIC to compensate for the decline in sales from the coronavirus pandemic.

See the chart on the right for operating income. With regard to expenses, the impact of the coronavirus pandemic was estimated at the time the forecast was formulated. However, as of last fall, we anticipated that the situation might improve during this fiscal year, and as a result, we have seen a decrease in expenses.

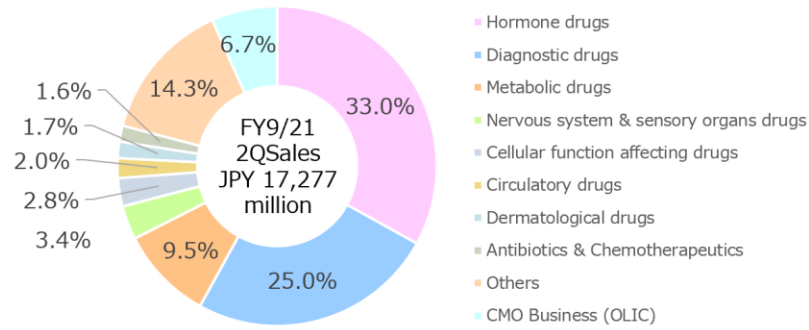
In addition, I have already mentioned research and development expenses. As a result of these changes, profits increased significantly compared to the forecast.

Sales by Therapeutic Category

(¥million)	FY9/17 First half	FY9/18 First half	FY9/19 First half	FY9/20 First half	**FY9/21 First half**	YoY Change Amount	YoY Change Ratio
Hormone drugs	4,764	5,290	5,278	5,053	**5,707**	654	12.9%
Diagnostic drugs	6,871	6,323	6,028	4,456	**4,315**	▲ 141	-3.2%
Metabolic drugs	1,405	1,442	1,505	1,572	**1,640**	68	4.3%
Nervous system & sensory organs drugs	0	82	449	593	**593**	0	0.0%
Cellular function affecting drugs	277	393	461	476	**491**	15	3.2%
Circulatory drugs	450	460	466	356	**346**	▲ 10	-2.8%
Dermatological drugs	189	198	265	277	**288**	11	4.0%
Antibiotics & Chemotherapeutics	413	409	397	368	**278**	▲ 90	-24.5%
Others	1,772	2,068	2,444	2,460	**2,465**	5	0.2%
CMO Business (OLIC)	1,179	1,293	1,186	1,290	**1,149**	▲ 141	-10.9%
Total	17,324	17,961	18,483	16,905	**17,277**	372	2.2%

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

Sales Breakdown by Therapeutic Category



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I will now talk about sales by drug class.

Since the previous fiscal year, hormone drugs have become the largest component of sales, but due to the decline in sales of Lunabell, the actual amount of sales declined. In the current fiscal year, we have seen a significant increase in sales due to a bottom-up focus on our core products.

I have already told you about contrast media and OLIC.

As for antibiotics and chemotherapy, a decrease in revenue was recorded due to the impact of the voluntary recall of Halizon syrup.

Sales of Major Products

Product Name (¥million)	Therapeutic Category	FY9/17 First half	FY9/18 First half	FY9/19 First half	FY9/20 First half	**FY9/21 First half**	YoY Change Amount	YoY Change Ratio	FY9/20 Budget	FY9/20 Progress Ratio
★IOPAMIDOL injection	Diagnostic drugs	3,508	2,947	3,580	3,342	**3,206**	▲ 136	-4.1%	6,444	49.8%
Filgrastim BS Injection Syringe	Metabolic drugs	839	847	945	1,097	**1,212**	115	10.5%	2,099	57.7%
★IOHEXOL injection	Diagnostic drugs	1,105	910	1,115	1,116	**1,109**	▲ 7	-0.6%	2,780	39.9%
DIENOGEST tablets	Hormone drugs	-	373	532	596	**830**	234	39.3%	1,275	65.1%
Favoir® tablets	Hormone drugs	283	335	328	464	**601**	137	29.5%	1,326	45.3%
GABAPEN® Tablets	Nervous system & sensory organs drugs	-	-	-	543	**538**	▲ 5	-0.9%	1,009	53.3%
Labellefille® tablets	Hormone drugs	191	223	316	393	**497**	104	26.5%	1,171	42.4%
LUNABELL® tablets (LD/ULD)	Hormone drugs	1,322	1,289	978	534	**472**	▲ 62	-11.6%	808	58.4%
DEXART® injection	Hormone drugs	427	431	435	434	**445**	11	2.5%	913	48.7%
◆UTROGESTAN® vaginal capsules	Hormone drugs	260	298	332	350	**442**	92	26.3%	859	51.5%
◆HMG intramuscular injection	Hormone drugs	422	447	400	365	**399**	34	9.3%	546	73.1%
LEVONORGESTREL tablets	Hormone drugs	-	-	47	326	**370**	44	13.5%	864	42.8%
◆FOLYRMON® -P injection	Hormone drugs	271	304	316	286	**295**	9	3.1%	592	49.8%
LIMAPROST ALFADEX tablets	Metabolic drugs	275	316	300	255	**241**	▲ 14	-5.5%	433	55.7%
◆BUSERELIN nasal solution	Hormone drugs	219	215	218	202	**216**	14	6.9%	422	51.2%
Total Top 15 Sales		9,130	8,933	9,842	10,307	**10,880**	573	5.6%	21,547	50.5%
Pct. Of Total Sales		52.7%	49.7%	53.2%	61.0%	63.0%			62.1%	
Other Products		7,013	7,734	7,453	5,307	**5,247**	▲ 60	-1.1%	11,274	46.5%
CMO Business (OLIC)		1,179	1,293	1,186	1,290	**1,149**	▲ 141	-10.9%	1,879	61.1%
Total		17,324	17,961	18,483	16,905	**17,277**	372	2.2%	34,702	49.8%
		2,034	2,316	1,245	0	**0**				

Acute Medical Care Women's Healthcare

★Product name change : OYPALOMIN® injection→IOPAMIDOL injection, IOPAQUE® injection→IOHEXOL 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

Next page. This slide shows net sales of major products.

As I have already mentioned, sales of contrast media have been decreasing, but sales of hormone drugs in the field of women's healthcare have been generally steady, with the exception of Lunabell, which is competing with generic products.

As the government is making preparations for insurance coverage in April 2022, and we are working to increase sales of infertility treatment drugs. As you can see, we are making steady progress.

FY9/21 2Q Summary of Consolidated Balance Sheet

(¥million)	FY9/20 Year End	FY9/21 End of 2Q	YoY Change Amount	YoY Change Ratio
Assets				
Current Assets	34,975	**34,430**	▲ 545	-1.6%
Cash and Deposits	12,041	**10,835**	▲ 1,206	-10.0%
Notes and Accounts Receivable - Trade	11,700	**12,165**	465	4.0%
Inventories	10,682	**10,780**	98	0.9%
Other	549	**649**	100	18.2%
Non-current Assests	26,987	**28,132**	1,145	4.2%
Property, Plant and Equipment	12,767	**13,672**	905	7.1%
Intangible Assets	2,899	**2,755**	▲ 144	-5.0%
Investments and Other Assets	11,320	**11,704**	384	3.4%
Total Assets	61,962	**62,563**	601	1.0%
Liabilities				
Current Liabilities	11,004	**18,954**	7,950	72.2%
Notes and Accounts Payable - Trade	3,680	**5,341**	1,661	45.1%
Other	7,324	**13,613**	6,289	85.9%
Non-current Liabilities	10,996	**11,043**	47	0.4%
Total Liabilities	22,001	**29,998**	7,997	36.3%
Net Assets				
Share capital	39,995	**32,163**	▲ 7,832	-19.6%
Capital Stock	3,799	**3,799**	0	0.0%
Capital Surplus	5,841	**4,408**	▲ 1,433	-24.5%
Retained Earnings	30,424	**24,560**	▲ 5,864	-19.3%
Treasury Shares	▲ 68	**▲ 603**	▲ 535	-
Accumulated Other Comprehensive income	▲ 37	**397**	434	-
Total Net Assets	39,961	**32,564**	▲ 7,397	-18.5%
Total Liabilites and Net Assets	61,962	**62,563**	601	1.0%

Borrowing for acquisition of treasury stock

Decrease due to acquisition and cancellation of treasury stock

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I would like to skip pages 10 and 11, and go to page 12.

The balance sheet as of the end of the second quarter is as shown here. One of the major changes was the change in the capital and liability structure due to the acquisition and cancellation of treasury stock from February to March.

FY9/21 2Q Summary of Consolidated Statements of Cash Flows

(¥million)	FY9/20 First half	**FY9/21 First half**	YoY Change Amount	YoY Change Ratio
Cash Flows from Operating Activities	2,442	**4,405**	1,963	80.4%
(Major Breakdown)				
Profit Before Income Taxes	423	**2,871**	2,448	578.7%
Depreciation	866	**978**	112	12.9%
Amortization of Goodwill	143	**138**	▲ 5	-3.5%
Loss (gain) on valuation of investment securities	1,172	**-**	-	-
Decrease (increase) in trade receivables	28	**▲ 425**	▲ 453	-
Decrease (Increase) in Inventories	▲ 1,246	**▲ 42**	1,204	-
Increase (decrease) in trade payables	1,224	**1,637**	413	33.7%
Income Taxes Paid	▲ 447	**▲ 387**	60	-
Cash Flows from Investing Activities	▲ 1,724	**▲ 2,018**	▲ 294	-
(Major Breakdown)				
Proceeds from sales of Investment Securities	-	**193**	-	-
Purchase of Property, Plant and Equipment	▲ 1,592	**▲ 1,800**	▲ 208	-
Purchase of Intangible Assets	▲ 138	**▲ 102**	36	-
Cash Flows from Financing Activities	▲ 3,133	**▲ 3,653**	▲ 520	-
(Major Breakdown)				
Purchase of Treasury Shares	▲ 0	**▲ 9,405**	▲ 9,405	-
Net increase (decrease) in Short-Term Loans Payable	-	**6,300**	-	-
Proceeds from Long-Term Loans borrowings	-	**1,000**	-	-
Repayments of Long-Term Loans borrowings	▲ 2,420	**▲ 836**	1,584	-
Cash Dividends Paid	▲ 467	**▲ 467**	0	-
Repayments of Lease Obligations	▲ 245	**▲ 243**	2	-
Cash and Cash Equivalents at Beginning of Period	8,494	**12,041**	3,547	41.8%
Cash and Cash Equivalents at End of Period	6,046	**10,835**	4,789	79.2%
Free Cash Flows	718	**2,386**	1,668	232.3%

Toyama Plant Capex

Acquisition of treasury stock due to dissolution of capital tie-up with Mitsui & Co.

Borrowing for acquisition of treasury stock

Next page. Cash flows for the first half of the fiscal year under review are as follows.

I have already talked about the acquisition and cancellation of treasury stock. Cash flow from investments related to the new formulation building at the Toyama Plant is proceeding as planned.

FY9/21 Consolidated Forecast

- Net sales : Expected to be in line with forecast, as strong sales of key women's healthcare products cover the impact of drug price revision and COVID-19
- Operating profit : Expected to be in line with forecast, as R&D expenses are delayed to the second half

(¥million)	FY9/20 Actual	**FY9/21 Forecast**	YoY Amount	YoY Ratio	**FY9/21 First half actual**	**FY9/21 Second half forecast**
Net Sales	33,793	**34,702**	909	2.7%	17,277	17,425
Operating Profit	3,139	**2,857**	▲ 282	-9.0%	2,686	171
Operating Margin	9.3%	**8.2%**	-	-	15.5%	1.0%
Ordinary Profit	2,983	**2,807**	▲ 176	-5.9%	2,738	69
Ordinary Margin	8.8%	**8.1%**	-	-	15.8%	0.4%
Profit Attributable to Owners of Parent	2,085	**2,100**	15	0.7%	2,021	79
Profit Margin	6.2%	**6.1%**	-	-	11.7%	0.5%
Capital Expenditure	2,965	**6,672**	3,707	125.0%	1,567	5,105
Depreciation (Inclusind Leased Equipment)	1,858	**1,581**	▲ 277	-14.9%	1,015	566
R&D Expenses	3,060	**3,200**	140	4.6%	861	2,339
R&D Expenses Ratio	9.1%	**9.2%**	-	-	5.0%	13.4%

※FY9/21 second half forecast is calculated by subtracting FY9/21 first half actual from FY9/21 forecast

Next page. This is the consolidated earnings forecast for the fiscal year ending September 30, 2021.

As we have already disclosed, profits increased significantly in the first half of the fiscal year, but the main reason for this was the postponement of research and development expenses.

Capital investment is also proceeding according to plan, with the strengthening of the Toyama Plant progressing as planned. As a result, there is no change to the full-year earnings forecast.

Although the impact of the NHI drug price revision in April 2021 on net sales is larger than expected, and is expected to be 6.2%, we will strive to achieve the forecast figures. We intend to focus on products in the field of women's healthcare, where sales are strong.

This concludes my presentation. Thank you very much.

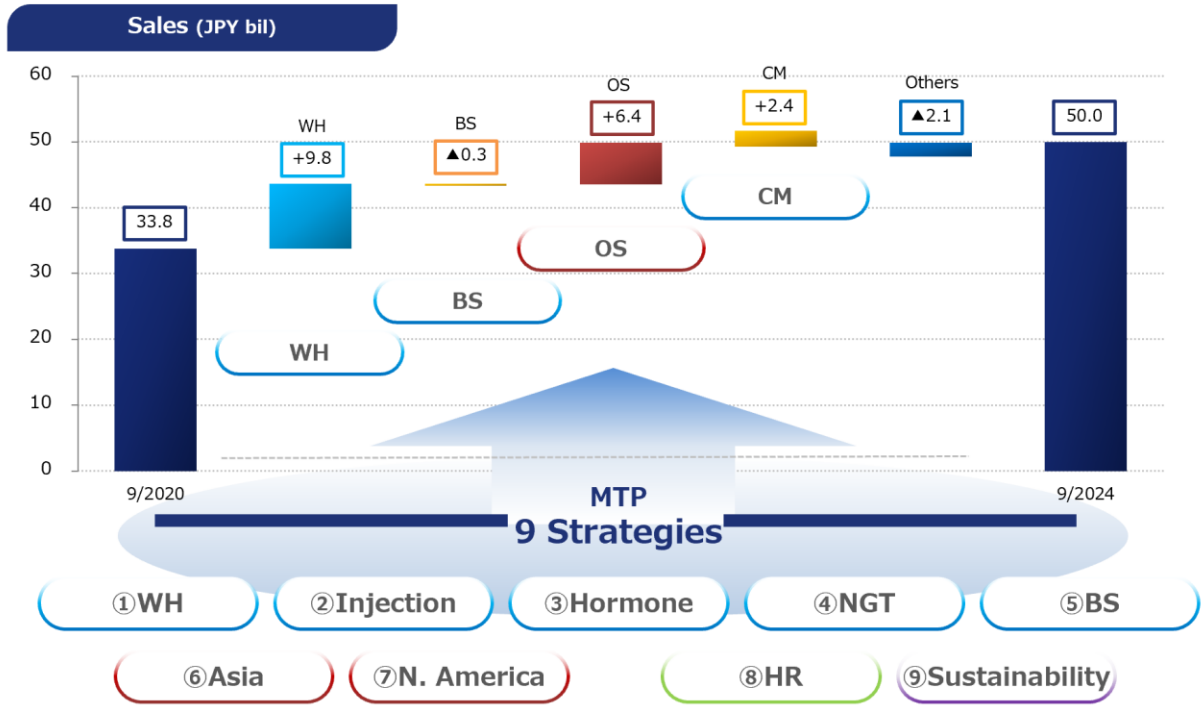
Iwai: Next, I would like to briefly explain our progress since last November in terms of the medium-term management plan.

This is the growth scenario for achieving the medium-term management plan announced in May last year. Our Mid-term Business Plan, which ends in the fiscal year ending September 30, 2024, is positioned as the midpoint of our goal of achieving consolidated sales of JPY100 billion in 10 years.

To achieve this, we are moving forward with 4 growth areas.

The first is to strengthen the field of women's healthcare. The second is to evolve into a sustainable contrast media business. Quantitative contributions will be made in the next Mid-term Business Plan, but we will establish the biosimilars business and strengthen our overseas business. The following slide outlines our medium-term management plan, which describes a plan to move forward in these 4 areas, culminating in the fiscal year ending September 30, 2024.

Financial Target (9/2024)



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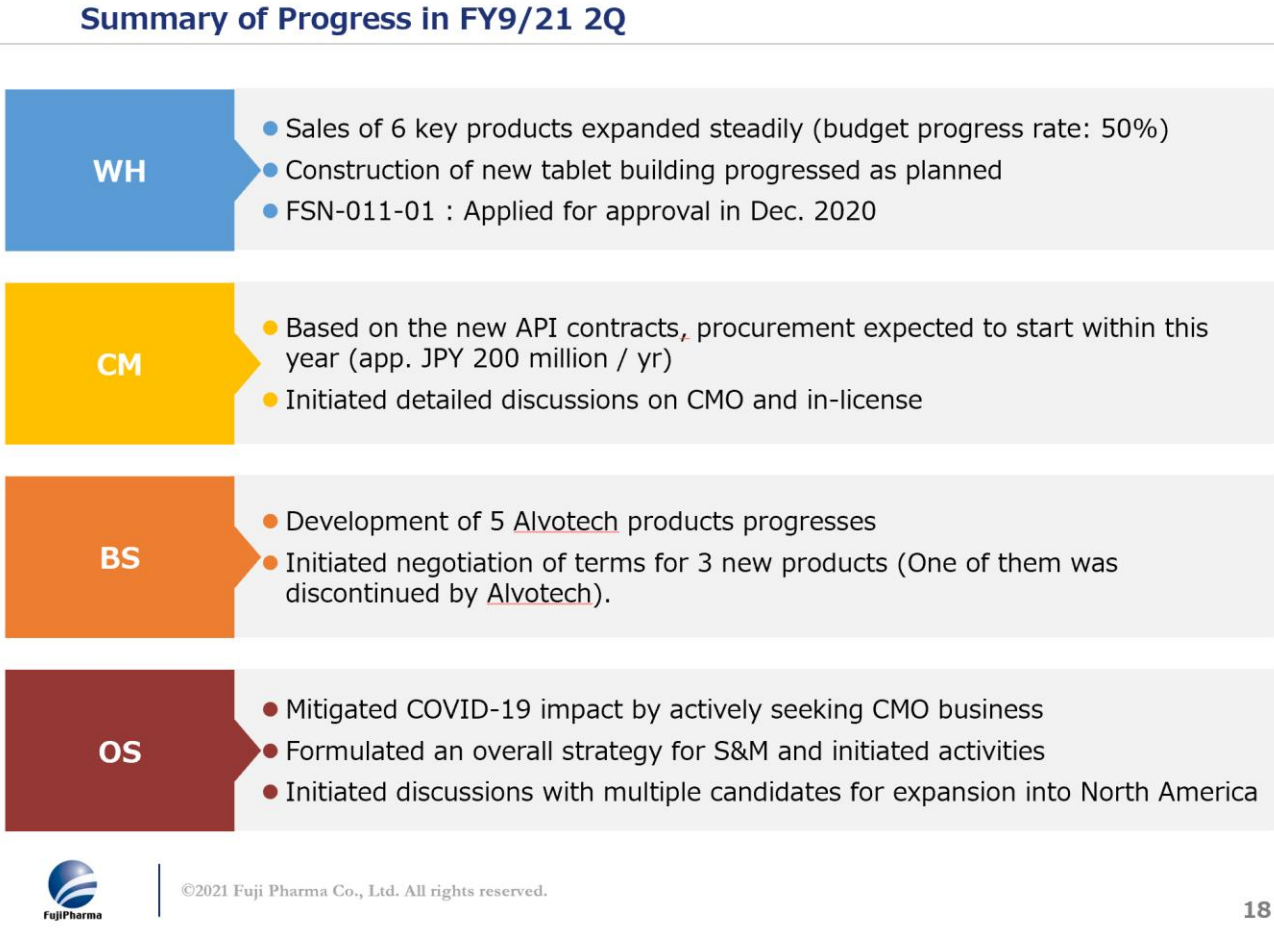
I will discuss the 4 areas I just mentioned.

The women's healthcare field will be important in achieving the current Mid-term Business Plan. As you can see here, we need to increase sales by JPY16 billion in order to achieve our target of JPY50 billion for the fiscal year ending September 30, 2024. Of this amount, about 60%, or JPY10 billion, is expected to be in the field of women's healthcare. This is the background for today's presentation, which will focus on women's healthcare, with a focus on environmental awareness and the new drug pipeline.



This slide shows the main themes for this part of the presentation. I would like to say a few words about each of the points that should be highlighted when discussing our progress in Mid-term Business Plan since November last year.

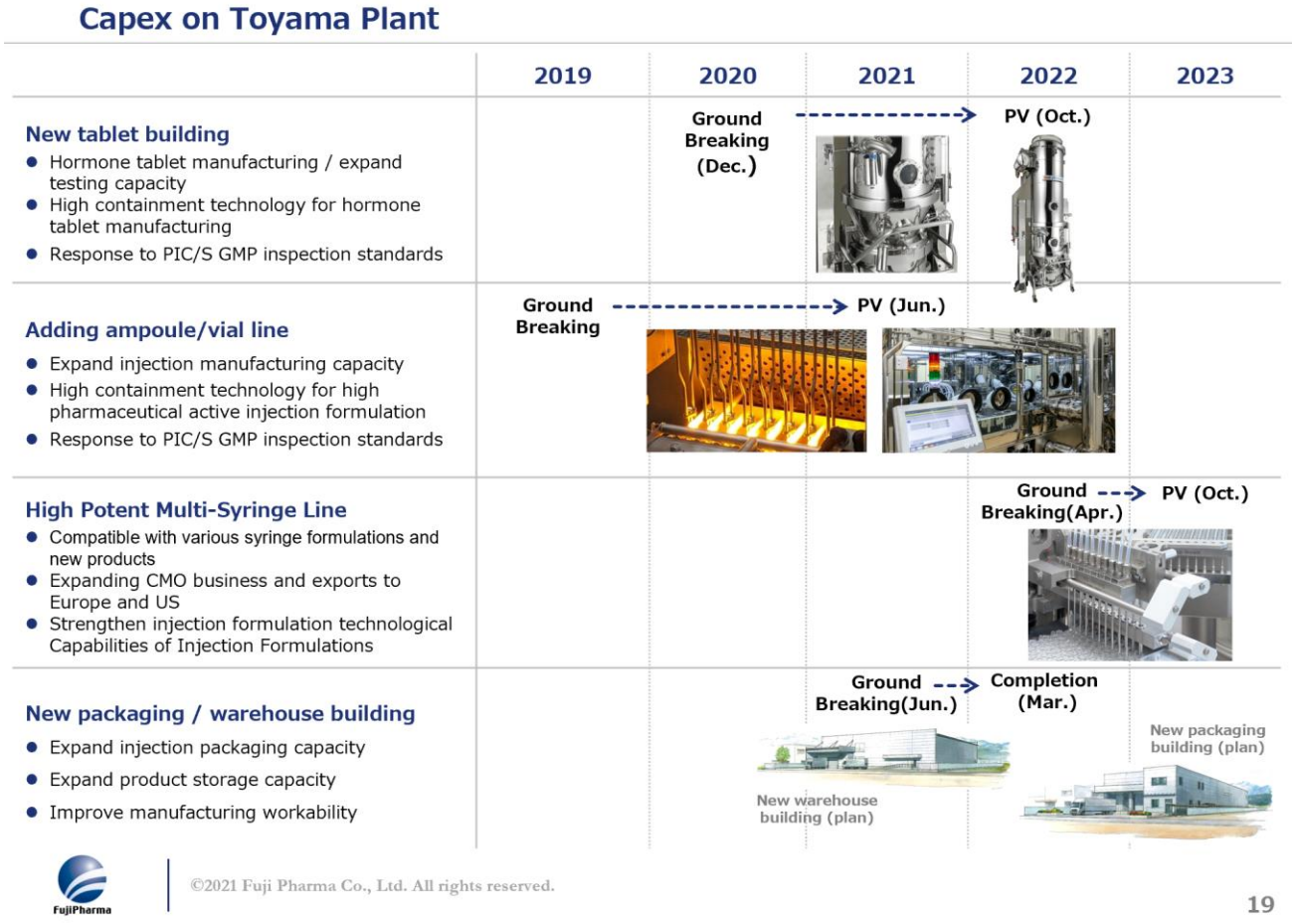
First, in the field of women's healthcare, we filed an application for FSN-011-01 in December last year. This will be explained in detail here. The demand for female hormone drugs is growing faster than expected, and in order to meet the increasing needs of patients and medical institutions, construction of a new formulation building to manufacture hormone drugs started last December as planned.

With regard to contrast media, in order to further reduce costs and ensure a stable supply, we have signed a new contract with a new API supplier. We plan to start procurement by the end of this year.

In the area of biosimilars, we mentioned last year that we signed a development agreement with Alvotech for 4 new products in Japan. The total number of development products in this area now numbers 5. Development is currently progressing smoothly.

Lastly, overseas, OLIC was temporarily affected by the coronavirus pandemic. The Company has mitigated the impact of this by adding new contract manufacturing, analysis, and quality control services. We are also in the process of filing an application for FSN-013, which I will explain later, in the summer of this year.

As for the Company as a whole, we are making generally smooth progress toward achieving our Mid-term Business Plan.

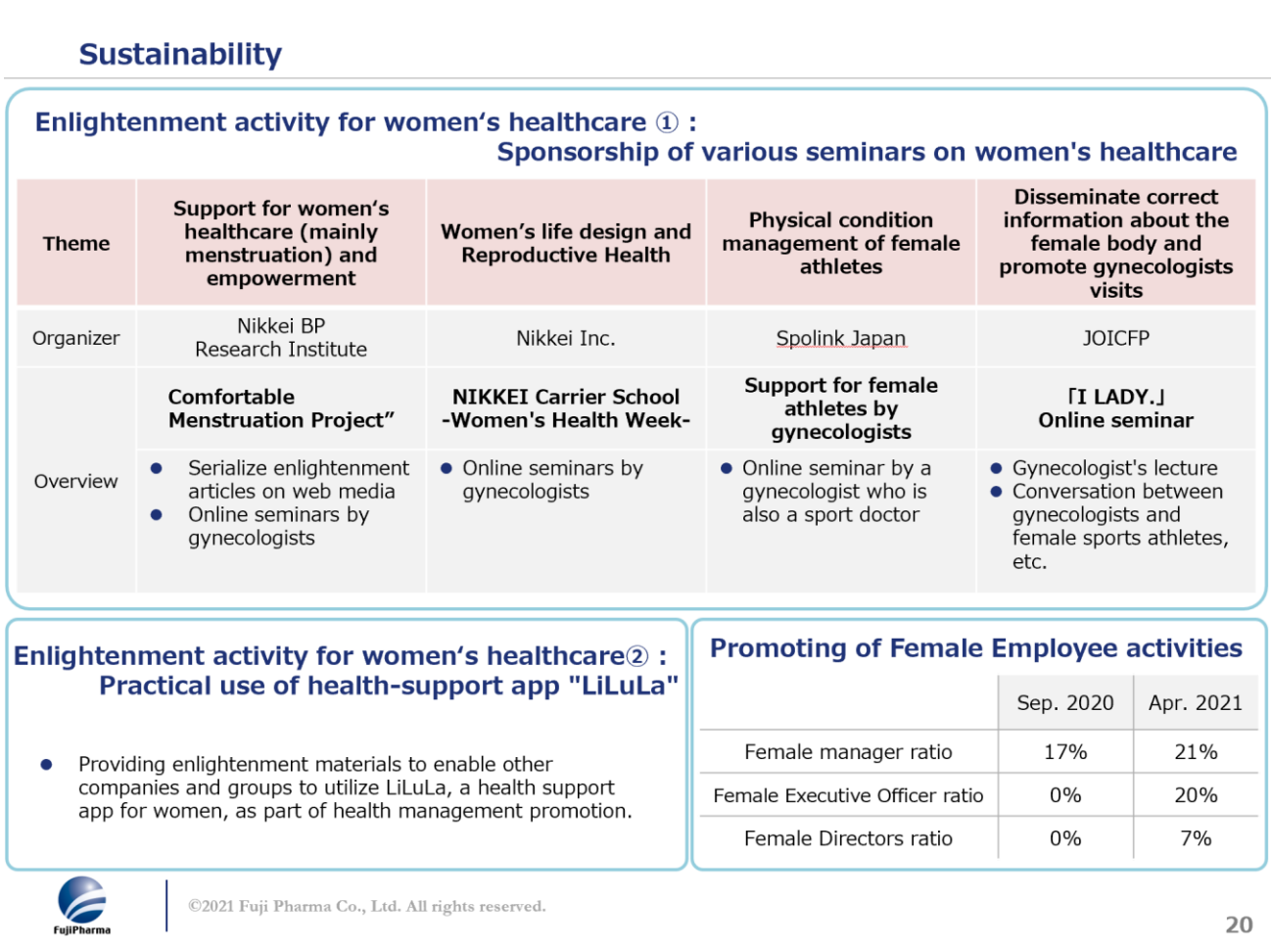


Next, I would like to talk a little about the status of capital investment in the Toyama Plant.

One of the highlights was the start of construction of the new formulation building last December. As Mr. Mitsuhashi will explain in more detail, the demand for hormone drugs for women's healthcare medical use has been increasing more than expected.

In December last year, we started construction of a new formulation building for the manufacture of hormone drugs to meet the needs of medical professionals and patients. Construction is scheduled to be completed in June of next year, and production will begin in October. With the start of production at the new facility, we will be able to triple our current manufacturing capacity and meet the needs of our customers.

As for injectable drugs, a new injection production line for highly pharmacologically active substances is scheduled to be completed in June of this year. In addition to our own products, we are planning to increase the number of commissioned services in Toyama.



Next, let's talk about sustainability.

Here is a summary of the major sustainability activities conducted in the first half of the year.

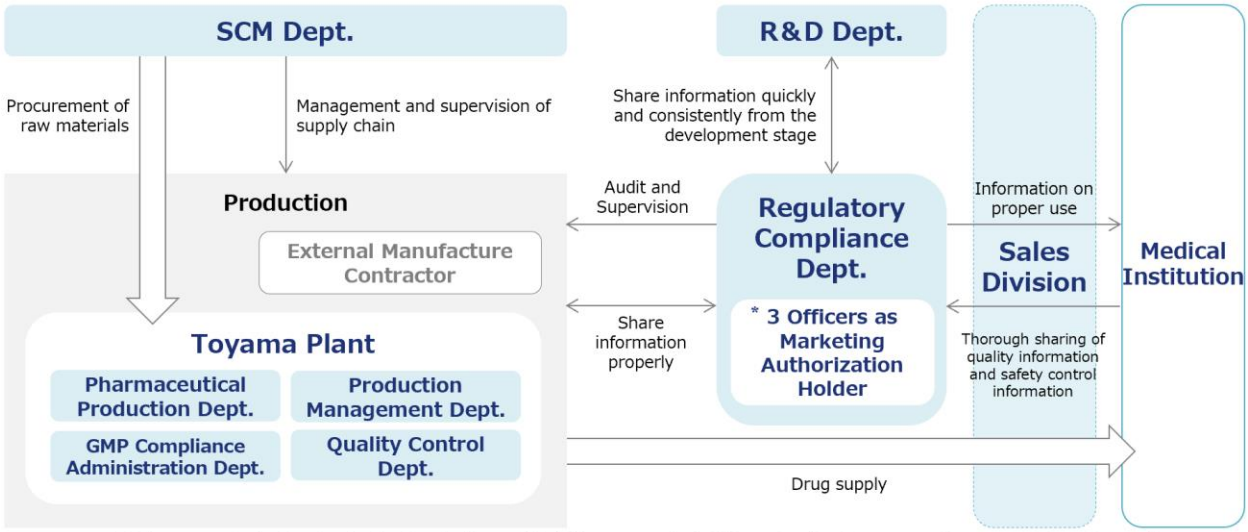
In the first half of the current fiscal year, we focused on raising awareness of the diversification of work styles and changes in lifestyles. We would like to support women in proactively choosing their own life plans, obtaining correct information about the mechanisms of their own bodies and diseases specific to women, and consulting medical institutions to deal with symptoms specific to women. Here are the activities for the first half of the year as I mentioned.

In addition, we are actively promoting the employment opportunities for women, as shown in the bottom right corner. Through these activities, we will continue to raise awareness of health issues specific to women.

Product control, quality control, and stable supply system

Constructing a system to provide safe and secure drugs for patients and medical professionals

- Regulatory compliance dept., which is responsible for important tasks in the safety control of drugs, a divisio under the direct control of President, and audits and supervises inside and outside activities.
- General Manager of Regulatory compliance dept., appointed as Chief Pharmaceutical Officer, conducts appropriate and timely reports and opinions on the safety management of drugs at executive officers meeting among others.
- SCM Dept. is responsible for supply chain management to ensure stable supply.



＊3 Officers as Marketing Authorization Holder : Chief Pharmaceutical Officer, Quality Assurance Manager, Safety Control Manager

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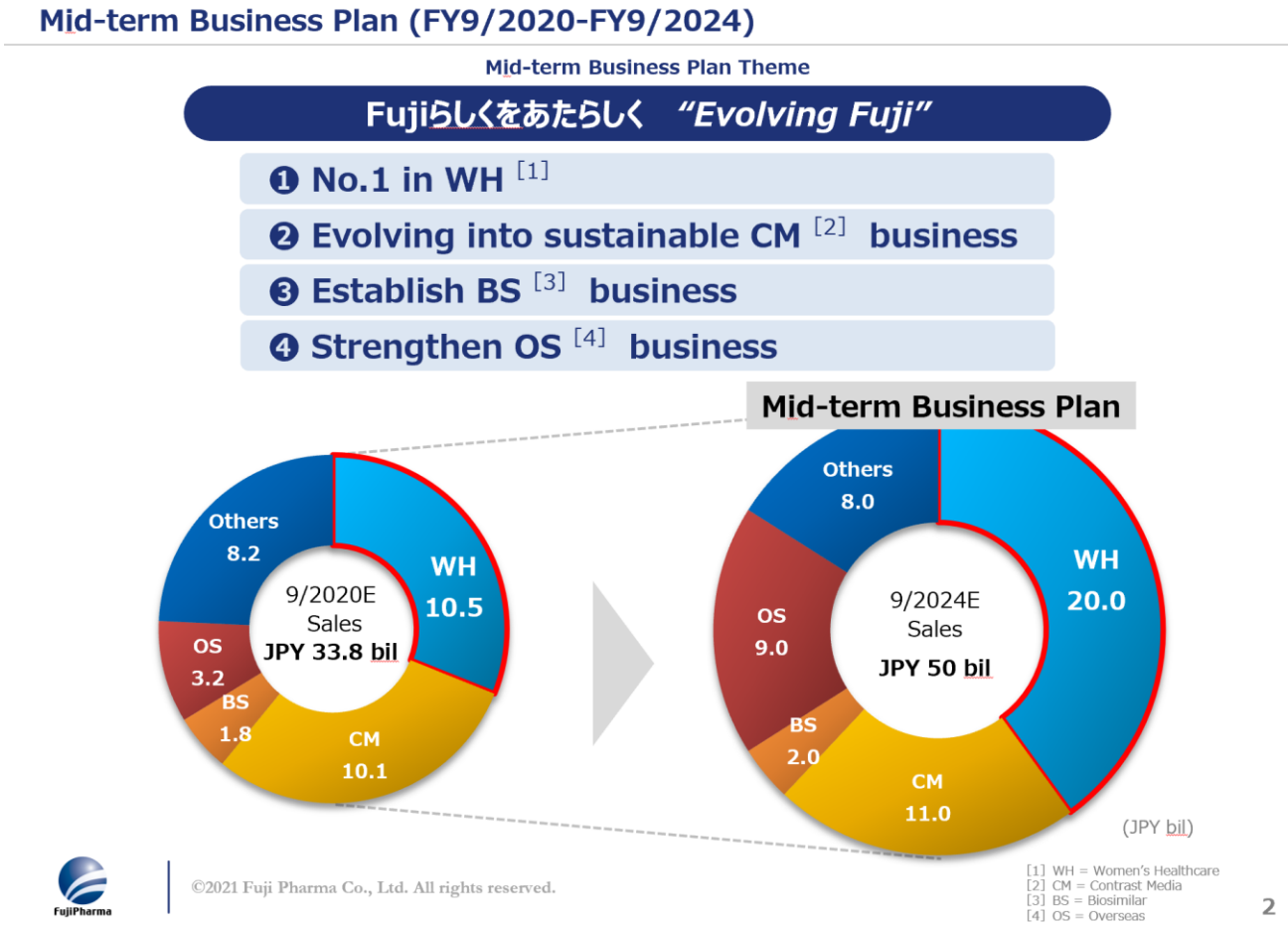
Lastly, I would like to talk a little bit about our manufacturing management, quality control, and safety supply system.

Last year, something happened that shook trust in pharmaceutical companies to the core. This incident should force all in the industry to review their own practices, and that is what we have endeavored to do. We are further strengthening our supply system to ensure that patients and medical institutions can use our products safely and with peace of mind.

In addition, I will personally visit company sites to urge employees to comply with GMP so that each and every one of them can perform their duties with a high level of awareness.

This is the progress of our medium-term management plan.



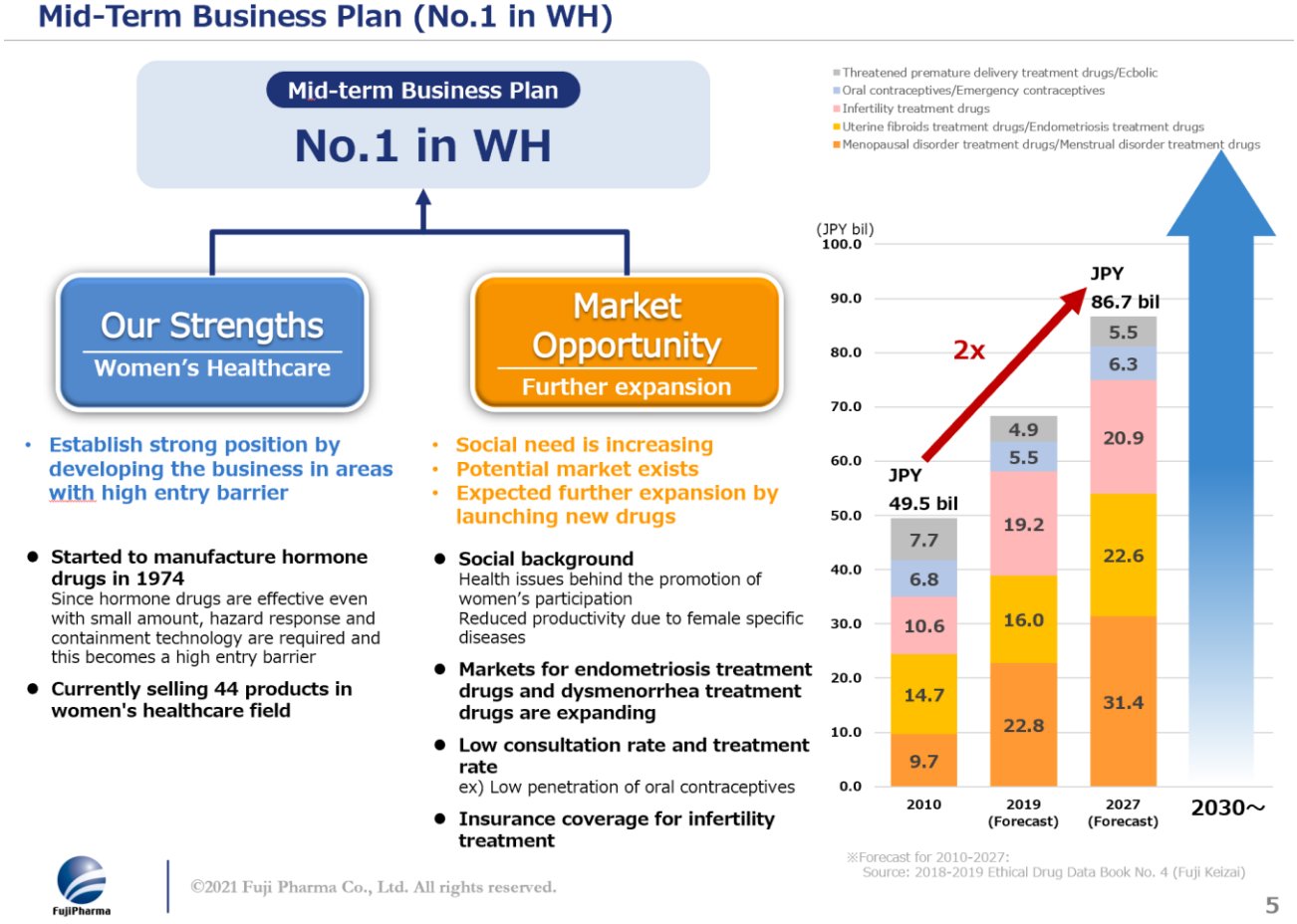
Now, let me move on to the second part. I would now like to focus on the new drug pipeline that we are currently developing. The upper part of this slide shows the 4 growth areas in the current medium-term management plan, as I mentioned earlier.

As I mentioned in the slide presentation in the first part, the percentage of sales in the women's healthcare segment is a very important factor in achieving our Mid-term Business Plan target of JPY50 billion in sales. We are planning to double the sales in of women's healthcare from the current JPY10 billion to JPY20 billion by March 2024.

In the area of women's healthcare, sales of Lunabell, our mainstay product for the treatment of dysmenorrhea, have been declining since its generic version was launched at the end of 2018. However, the needs of patients and medical institutions for hormone drugs, including oral contraceptive drugs and dysmenorrhea treatments drugs, have been growing much faster than we expected or imagined.

In addition, the start of clinical trials for post-Lunabell products has also taken shape, so I would like to take this opportunity to explain the market trends in this field and our new drug development status in this field, so that you can better understand our efforts to realize our Mid-term Business Plan. In the second part of the presentation, I will focus on women's healthcare.

Mr. Mitsuhashi will explain about the market environment first, and then Mr. Naganawa will explain about the development status of the development pipeline. Thank you.



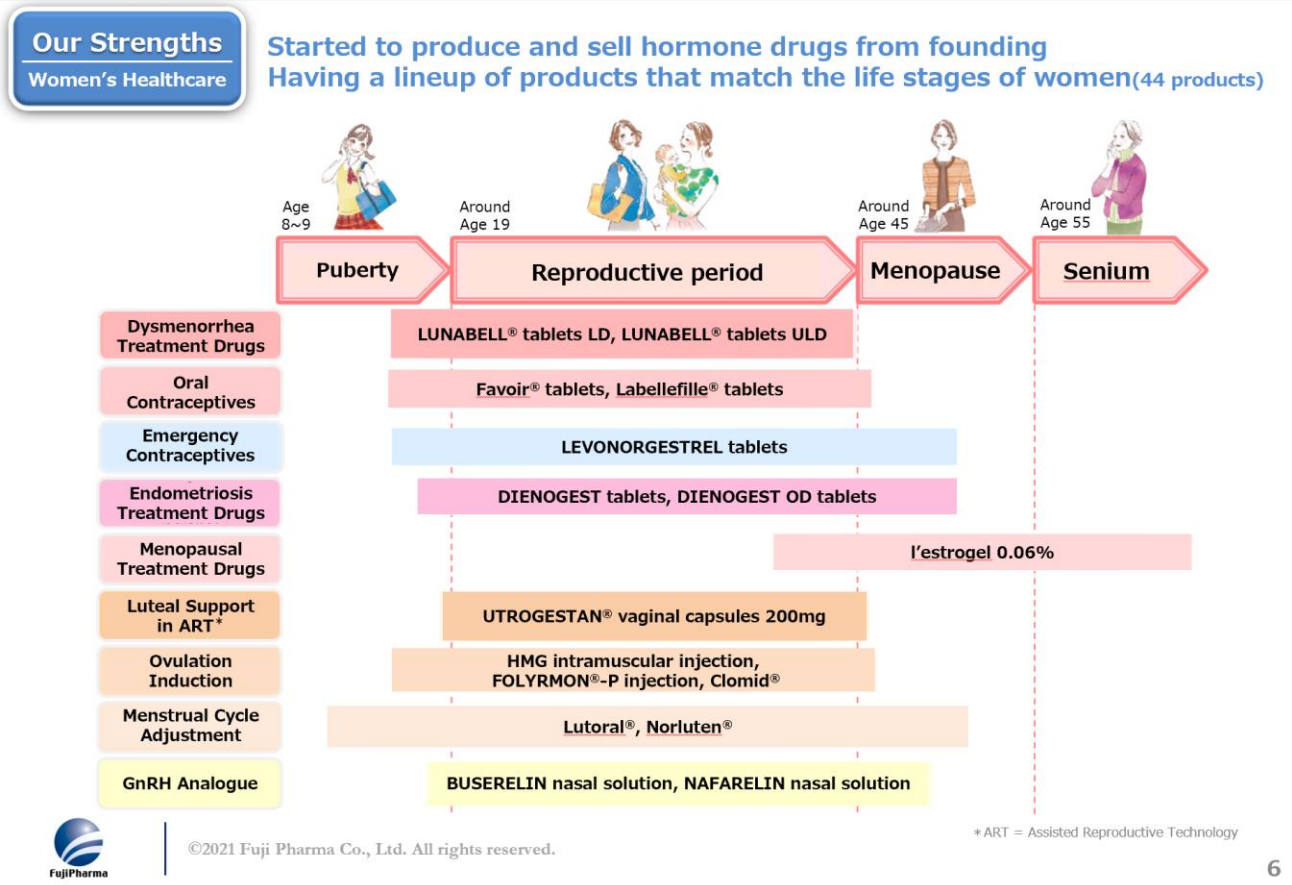
Mitsuhashi: Hello. Thank you for your cooperation.

I would like to explain the market environment in the field of women's healthcare and our target product portfolio to achieve our Mid-term Business Plan.

Our strengths include our hormone formulation technology, manufacturing facilities, and broad product lineup in the field of women's healthcare. We also have strong relationships with obstetricians and gynecologists. Based on these strengths, we will aim to become the number one company in the field of women's healthcare by further developing our portfolio for the market of women's healthcare areas with high growth potential.

As shown in the graph on the right, the market for female-specific diseases is on the rise. We aim to further expand the market by launching new drugs and generics that make a significant contribution to medical care, while at the same time working to uncover potential markets.

Our Strengths

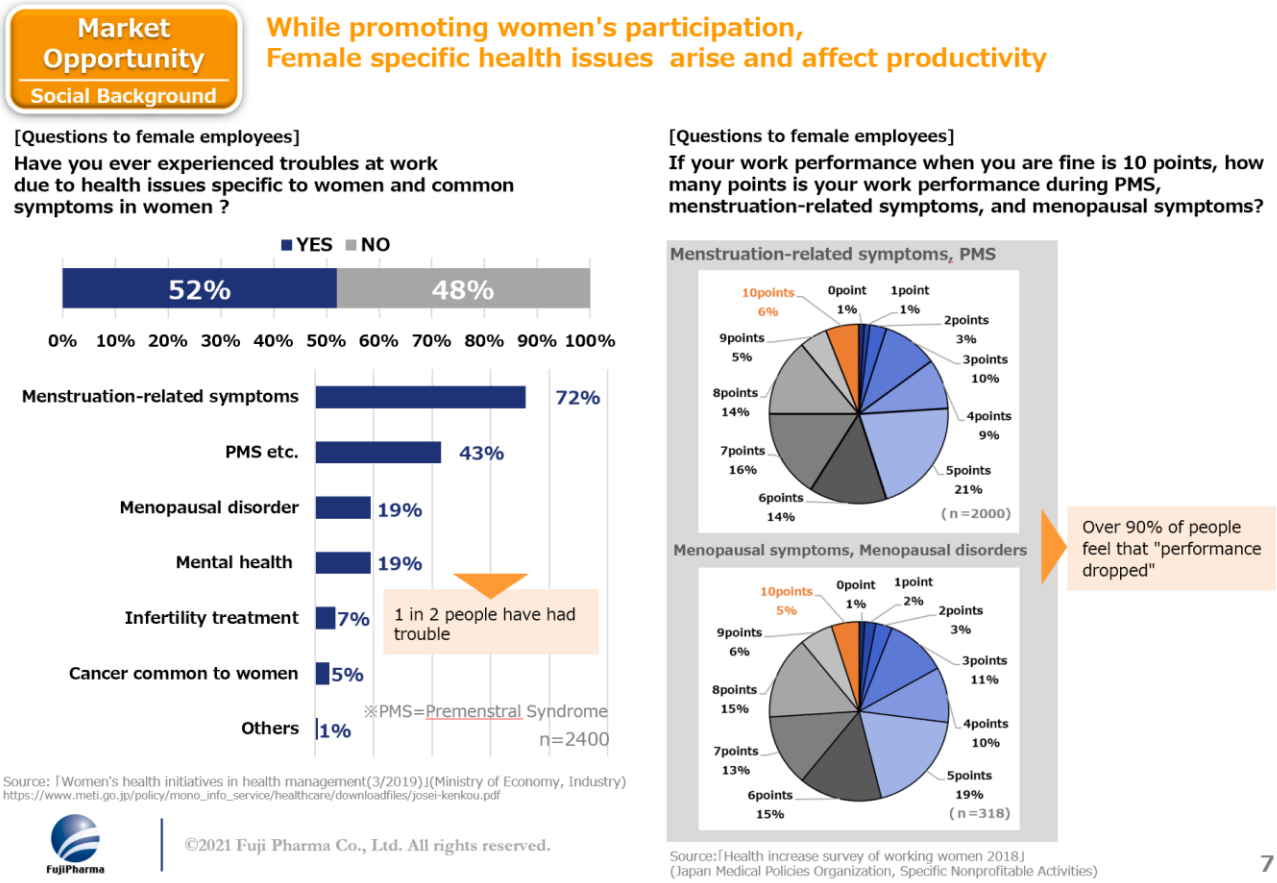


Here is our current product lineup.

We have products that are necessary for each stage of women's lives. At present, there are 44 products in total. New drugs are Lunabell Combination Tablets, l'estrogel, Clomid, and Utrogestan, and the others are generic items.

By combining new drugs and generics in this way, we have built up our lineup so that we can provide a treatment option at each stage.

Market Opportunity (Social Background)



First, let me introduce the social background, which is important when considering the market.

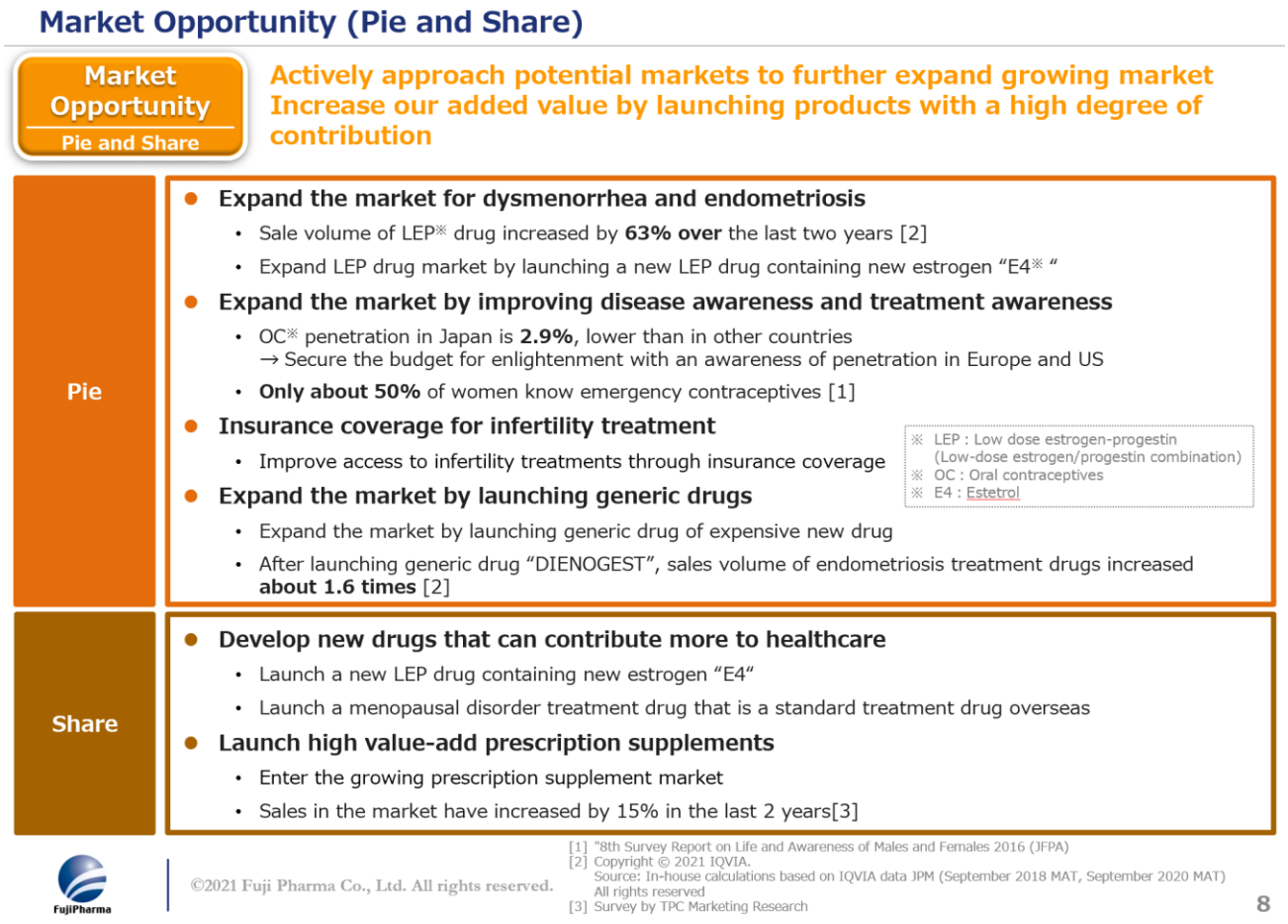
While companies are promoting work style reforms and health management, and expanding opportunities for women to play an active role, various data also show that health issues specific to women are coming to the fore.

The graph on the left shows a survey of workplace conditions for working women. When working women were asked if they had experienced any problems at work due to female-specific symptoms, about 50% of them answered that they had experienced some kind of problem.

The breakdown shows that other than mental health, the other problems are specific to women, with 70% of women experiencing problems with menstruation-related symptoms and disorders. In addition, premenstrual syndrome, menopause, infertility, and fertility also prove to be a issues for many working women.

The pie chart on the right shows the results of a survey on work performance. This is the result of asking people to score their work performance when they are healthy as 10 points, and their work performance when they have each symptom. The top row is for menstrual symptoms, and the bottom row is for menopause. For both of these, roughly 95% of women said these symptoms reduced their work performance. Of those, one in 2 answered that the score dropped to 5 points or less, suggesting that work performance drops by at least half for this group.

This situation suggests that the long-term neglect of women's healthcare issues and women-specific diseases may impair labor productivity. We are committed to solving this social issue by providing appropriate information as well as superior pharmaceutical products.



We are also examining the marketability of our product portfolio based on this point.

Among the markets related to female-specific diseases, the growth of dysmenorrhea treatments drugs is particularly significant, with a 63% increase in volume over the last 2 years.

As dysmenorrhea treatments drugs, we are developing a LEP formulation containing a new hormone, E4 (estetrol). This drug is said to be characterized by its low impact on the blood coagulation system, and we believe that further market expansion is possible by promoting its safety.

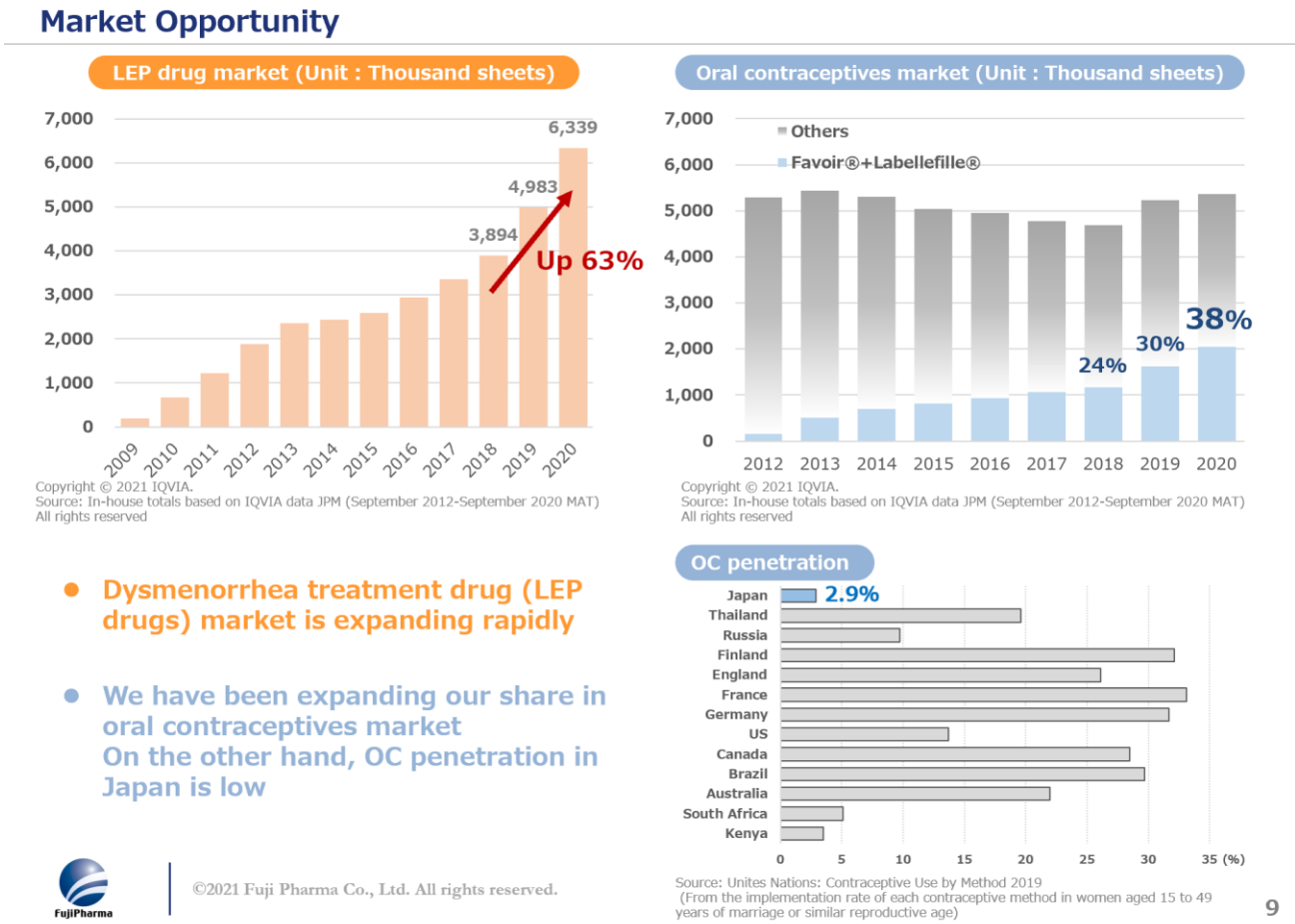
In addition, awareness of female-specific diseases and treatment is still low in Japan. We will work to expand the market by increasing awareness. OC (oral contraceptive drugs) use is low compared to other countries. We will continue to promote awareness-raising activities while aiming to achieve similar levels of use as in Europe and the United States. We have budgeted the expenses for this in our Mid-term Business Plan.

Furthermore, we believe that the insurance coverage for infertility treatment, which is being promoted mainly by the government, will lead to improved access to medical institutions for women who are pregnant, infertile, or trying to conceive. On the other hand, since the scope of insurance coverage has not been clearly defined, the impact on our business is unclear in some areas, but we will take measures for our portfolio in accordance with future developments.

In addition to new drugs, there are many cases in the women's healthcare field where the market is expanding due to the launch of generics. In addition to switching to brand-name products, we are always looking to expand the market with generics.

For example, the number of prescriptions for dienogest, endometriosis treatment drugs, increased by a factor of 1.6 in Japan after the launch of a generic version. This is a situation where prescriptions numbers had not progressed significantly due to the heavy burden placed on patients by the high drug prices. However, with the low drug price of the generic, prescriptions picked up to a more acceptable level.

In line with the expansion of these markets, we are planning to add new products to our product pipeline, including new drugs that will make a significant contribution to medical care, and prescription supplements with high added value. We are progressiong with these steps with the aim of capturing a large share of each market.



Here is data on dysmenorrhea treatments drugs (LEP) market and the prevalence of oral contraceptive drugs, as mentioned earlier.

The Company has created a new market for LEP products with Lunabell combination tablets. This market has grown to about 6.3 million sheets in FY2020. This is more than the number of sheets of oral contraceptive drugs. Although the penetration rate of oral contraceptive drugs in Japan is low at 2.9% compared to other countries, the number of sheets is on the rise, and our share of this market has increased to 38%.

Product Pipeline up to FY9/2024 (Women's Healthcare)

- Having a full lineup of Women's Healthcare products that match the life stages of women
- Develop new drugs that have the potential to expand market

＊－Underlined part: New drug

	Growth expectations (Environment and Element)	Products under development New products		6 key products	Others
Dysmenorrhea Endometriosis	• LEP drug market : Up 63% in last 2 years • Launch a new LEP drug containing new estrogen "E4" → LEP drug market expands further	**FSN-013** ※Planned to launch in 2024	Marketing rights and product acquisitions	DIENOGEST	Existing products : 38 items
Menopausal disorder	• Launch a natural progestogen drug → Overseas standard treatment drug become treatment option	**FSN-011-01** GE : 1 items Supplement : 1 item		l'estrogel	
Oral contraceptives **Emergency contraceptives**	• OC market : Up 14% over in last 2 years • Actively approach potential markets → Secure the budget for enlightenment → Expand online medical care			Favoir® Labellefille® LEVONORGESTREL	
Infertility treatment	• Insurance coverage for infertility treatment	GE : 1 items Supplement : 1 item		UTROGESTAN®	
Others (Perinatal period, etc.)		Medical materials : 1 item			
	FY9/2020 Net sales (Plan) → **FY9/2024 Net sales (Plan) →**	**0** ↓ **5 billion**		**5 billion** ↓ **10 billion**	**5 billion** ↓ **5 billion**

FY9/2024
JPY 20 billion

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Finally, I would like to introduce our product portfolio up to the fiscal year ending September 30, 2024, which is the final year of our Mid-term Business Plan.

In the future, we plan to launch 7 new products in the field of women's healthcare. These products are related to dysmenorrhea, menopause, infertility treatment, and perinatal care. We plan to offer not only prescription drugs but also supplements and other medical products.

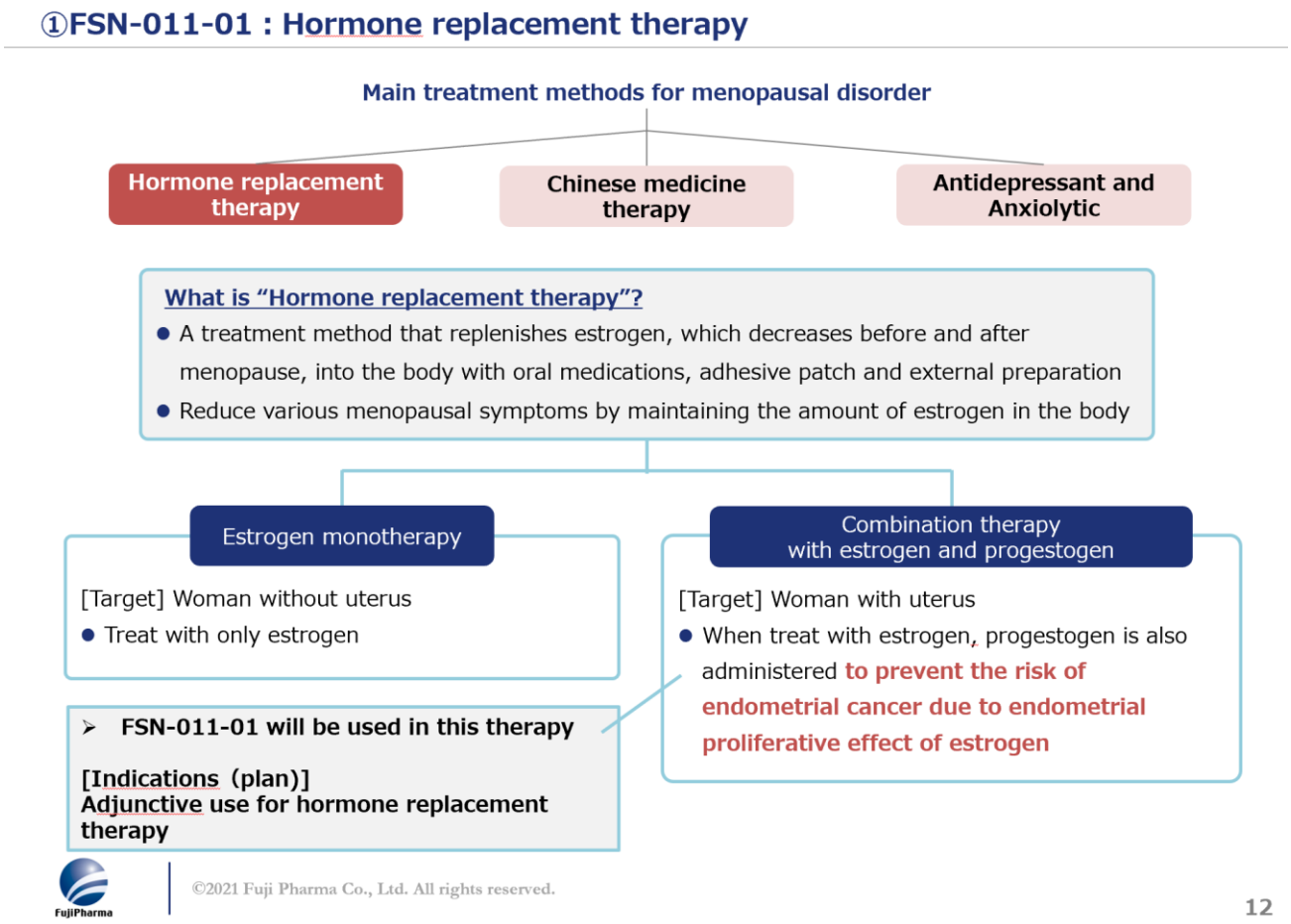
This is the first time we have started working on supplements. In the future, we will actively develop preventive medicine as well as therapeutic medicine. This supplement is positioned as a dietary supplement that is prescribed by doctors. We are planning to add new ingredients to the existing ones to provide high value-added products whose use is backed up by evidence and that are made according to our high standards as a pharmaceutical manufacturer.

As Mr. Naganawa of the Research & Development Division will explain later, the 2 new drugs are also products that can fully meet medical needs.

FSN-013 is being developed as dysmenorrhea treatments drugs using E4, and is the first effort in the world to develop a formulation of E4 for this indication. In addition, FSN-011-01 has been prescribed as a standard treatment for a little while overseas, and we plan to start marketing it in Japan by the end of this year.

We plan to grow our women's healthcare business to JPY20 billion by adding JPY5 billion from 7 new products and JPY5 billion from the growth of 6 major products. This is in addition to the JPY10 billion in sales for the fiscal year ending September 2020.

That concludes my presentation. Mr. Naganawa will now discuss the details of our product pipeline.



Naganawa: Hello. Thank you. I would like to explain about FSN-011-01 and FSN-013, 2 products we are currently developing in the field of women's healthcare.

First, let's talk about FSN-011-01. Menopause is a physical and mental condition that occurs in women in their 40s and 50s, around the time of menopause, due to a decrease in follicular hormones. There are 3 main treatment methods, as shown here. This drug is the type on the left, hormone replacement therapy.

Hormone replacement therapy is a treatment method that replenishes the body with hormones that are low around the time of menopause through medication, creams, or ointments. By maintaining the amount of follicular hormones in the body, it reduces various symptoms of menopause.

There are 2 ways to administer the drug, as shown in the bottom row. This depends on whether an individual has had a hysterectomy. On the left is the treatment method for those who have had their uterus surgically removed, and in this case only follicular hormone drugs are administered.

On the other hand, for those who have a uterus, a combination of follicle hormone and progestin is used. This is due to the fact that follicular hormone causes the endometrium to proliferate, and there is a risk of developing uterine cancer with long-term treatment. The main ingredient of FSN-011-01 is progestin, which is used to prevent uterine cancer.

①FSN-011-01 : Product Summary

Background

- No progestogen drug for hormone replacement therapy
- JSOG and JSMWM submitted development request for hormone replacement therapy
  A development request product certified as having high medical need at the Evaluation Committee on Unapproved or Off-labeled Drugs with High Medical Needs
- A drug that are also listed in the Guidelines and are used as standards in other countries
- Approved and launched in over 100 countries (e.g. the US and EU)

Characteristics

- The first oral capsule drug micronized with natural progestogen in Japan
- Compared to synthetic progesterone, **it has a lower risk of breast cancer and is safer**
- Compared to synthetic progesterone, it has no adverse effect on lipid profile or vascular endothelial function

Development in Japan

- Phase III was completed, and in December 2020, we applied for "Adjunctive use for hormone replacement therapy" as an indication.

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The following is an overview of FSN-011-01.

Currently, there is no single agent that is indicated as an adjunct to hormone replacement therapy. Until now, synthetic progestins, which are chemically modified versions of naturally occurring progestins, have been used off-label. However, due to concerns about side effects, Japan Society of Obstetrics and Gynecology and Japan Society for Menopause and Women's Health have requested the development of this drug.

It is a drug that was recognized as having a high medical necessity at a national review meeting for unapproved and off-label drugs. Our Company subsequently took on its development.

This drug is also listed in overseas guidelines, and as I explained earlier, it is a standard drug. It is also approved and sold in 100 countries around the world, including in the United States and EU member countries.

It has the same chemical structure as the luteinizing hormone produced in women's ovaries, and we call it a natural luteinizing hormone.

This ingredient is known to have a lower risk of breast cancer and is safer than synthetic progestins. It also has less of the adverse effects on lipids and vascular endothelial function seen with synthetic progestins.

In Japan, Phase III trials were completed in 2020, and an application for approval was filed in December for the planned indication of adjuvant to hormone replacement therapy. It is currently under review.

①FSN-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-randomised, 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	Oral administration before bedtime for 52 weeks ① From day 1 to day 28, administer 100 mg of FSN-011-01 once daily（1 cycle=28 days） 1 cycle (28 days) Estrogen: Estrogen drug (E2 tablet) 0.5 or 1.0mg/day Progestogen: **FSN-011-01 100mg 1 tablet/day** ② From day 15 to day 28, administer 200 mg of FSN-011-01 once daily（1 cycle=28 days） 1 cycle (28 days) Estrogen: Estrogen drug (E2 tablet) 0.5 or 1.0mg/day Progestogen: Dose interruption for 14 days / **FSN-011-01 100mg 2 tablets/day**
Evaluation items	Primary endpoint : Incidence of endometrial hyperpiasia without atypia Secondary endpoint : Thickness of endometrium during the dosing period Safety endpoint : Incidence of adverse events and adverse drug reactions
Result	No endometrial hyperpiasia without atypia was observed with any administration methods

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This gives some information on the details of the Phase III trials conducted in Japan.

Although approved overseas, there is no oral formulation of natural progestin in Japan, so we are conducting Phase III clinical trials in Japan for women who are eligible for hormone replacement therapy in Japan.

The study design is a non-randomized, open trial. The total number of cases administered was 328, 161 with the continuous administration method and 167 with the cyclic administration method.

As for the dosage and administration method, as stated in the dosage and administration in the middle of this slide, one cycle is 28 days. In the continuous dosage method, the patient takes the follicular hormone preparation and the progestin preparation every day for that period of time. In the cyclical dosage method, the patient takes the follicular hormone preparation every day for 28 days, and to takes this drug for the second half of the cycle, from day 15 to day 28.

The primary endpoint looked at the incidence of endometriosis. Specifically, a sample of endometrium was taken, and pathological examination was performed to evaluate changes in the tissue.

No endometrial hyperplasia was observed in any of the administration methods. This means that the efficacy of this drug has been confirmed in Japanese patients.

②FSN-013 : Product Summary

Overview

- Next-generation OCs (oral contraception) to novel dysmenorrhea drugs
- 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.
- Combination with progesterone (drospirenone)
- Approved in the U.S. and Canada, and received a recommendation of approval in Europe (EMA)

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 : In preparation for Phase III

Launch : 2024 (target)

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Next, I would like to explain about FSN-013. This drug is being developed overseas as a next-generation oral contraceptive drugs, and in Japan as dysmenorrhea treatments drugs.

This drug is a combination of estetrol, a follicular hormone with a unique action, and drospirenone, a progestin.

Estetrol is expected to reduce the side effects commonly reported with concomitant use of estrogen, which has traditionally been used in low-dose oral contraceptive drugs and dysmenorrhea treatment drugs.

The drug is used oral contraceptive drugs overseas and has been approved in the U.S. and Canada. In Europe, a recommendation for approval has been issued.

Estetrol has been found to have less effect on the blood coagulation system than existing drugs. Estetrol is also characterized by minimal drug interactions. It is also characterized by good bleeding control and lipid effects, and low weight gain.

In Japan, the drug is being developed for use in the treatment of dysmenorrhea, as well as pain associated with endometriosis. Preparations are currently underway for Phase III trials. Development is underway with the goal of launching the product in 2024.

②FSN-013 : About Estetrol

- 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 ERβ is 4-to 5-fold more affinity for ERα.
- Estetrol selectively activates nuclear ERα (membrane ERα is not activated).
- With these selectivities, various benefits are expected.
- This is called Natural Estrogen with Selective Action in Tissues (NEST)

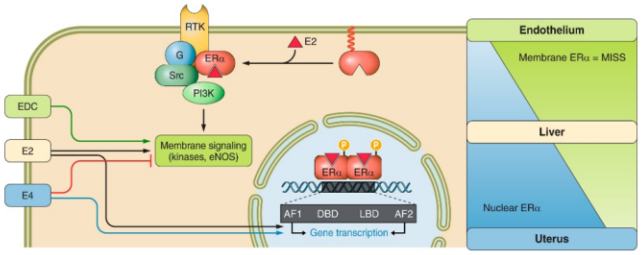
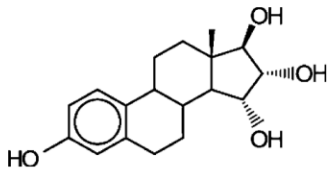


Figure)Arnal et al., Physiol Rev 97 : 1045-1087, 2017



Structure of Estetrol

Here is an explanation of Estetrol.

Estetrol is a newly-developed treatment that will be used in the future. The discovery of the compound itself dates back to 1965. It was found in the urine of a pregnant woman.

This substance is metabolized in the liver of the fetus and is transferred to the mother through the placenta, and is detected in maternal urine from the 9th week of pregnancy.

Estetrol's estrogenic activity has been found to be weaker than that of other follicular hormones.

On the other hand, estetrol has been found to selectively act on estrogen receptors, binding to and activating estrogen receptors in the nucleus. On the other hand, it is unique in that it binds to membrane receptors but does not activate them.

This selectivity is expected to provide a variety of benefits.

It is also called NEST because it is a new follicle hormone. This product, FSN-013, uses an ingredient that has the same chemical structure as this compound.

②FSN-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

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Now, I would like to explain about the Phase III trials that we will be conducting.

2 Phase III trials are planned. This is a study to evaluate the safety and efficacy of the drug for dysmenorrhea. The design of the study is a multicenter, double-blind, placebo-controlled trial. The number of patients will be 150, and the allocation of patients will be done by dividing them 1:1 into real drug and placebo groups.

In the real drug group, patients receive the real drug for 24 days, followed by placebo for 4 days. The placebo group will receive placebo tablets for 28 days.

The primary endpoint will be the change in dysmenorrhea score in the first 4 cycles after drug administration compared to placebo, using the dysmenorrhea score before drug administration as the baseline value. In addition, the safety of long-term administration is to be confirmed for the following 13 cycles, which will be 52 weeks.

②FSN-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

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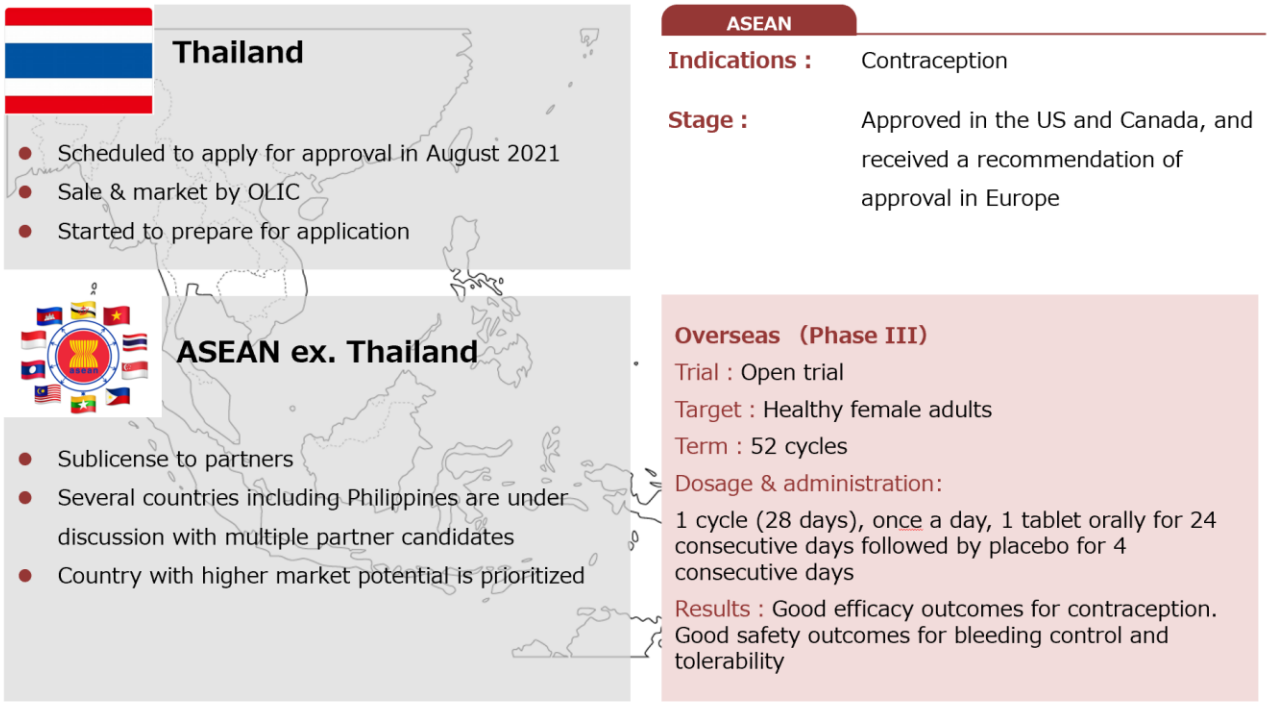
This is the second trial. This trial is designed to assess the effect on pain associated with endometriosis.

We are working on a similar design to the dysmenorrhea study I mentioned earlier.

The primary endpoint will be pelvic pain before drug administration, and the change in pelvic pain at 24 weeks after drug administration, on the sixth cycle, will be compared with placebo. In addition, we plan to confirm the safety of long-term administration for 13 cycles, or 52 weeks.

These 2 tests are scheduled to be held next month, from June onwards.

②FSN-013 : ASEAN Business Plan



Next, I would like to explain the outlook for ASEAN. In ASEAN, we are aiming to launch the product for the indication of contraception.

In Thailand, we are planning to file an application in August this year, and after approval, OLIC plans to market the product in-house. We are currently in discussions with the Thai authorities to obtain permits.

In ASEAN countries other than Thailand, we plan to sell the product through sublicensing. We are in discussions with several companies in several countries in addition to the Philippines regarding specific conditions. Priority for discussions will be given to countries deemed to have market potential.

In both Japan and ASEAN, we will work towards the early launch of this product.

This concludes my presentation on the new drug pipeline. Thank you very much for your attention.

Moderator: Thank you all.

Question & Answer

Moderator: Thank you all. We will now move on to the question-and-answer session. Please feel free to ask any questions you may have in the text chat.

I would like to introduce the first question. It is as follows.

“Could you tell us why R&D expenses are much lower than the previous fiscal year, why the progress rate against the budget is low, and what your outlook is for the full year?”

Iwai: I would like to answer this question. The main reason for the low R&D expenses in the previous fiscal year was that the contract for the project we are currently working on to obtain a license from overseas and obtain approval in Japan was scheduled to be signed in March, but this was postponed to the third quarter.

On the other hand, negotiations in this area are progressing smoothly, so on a full-year basis, we expect R&D expenses to be as originally planned.

Moderator: Thank you very much. Now I would like to introduce the next question.

“Please tell us about the progress of the government's consideration of insurance coverage for infertility treatment and how it will affect your company.”

Iwai: Thank you for your question. I will pass this to Mr. Sato.

Sato: Thank you for your question. As for infertility treatment, as was mentioned in the explanation, it is expected to be covered by insurance from April 2022. The Ministry of Health, Labor and Welfare (MHLW) disclosed the results of a survey and research on the current situation in April, which you may have seen.

I understand that the academic societies are planning to prepare and publish guidelines by the summer of this year. In this context, I understand that full-scale discussions will be conducted.

As for the impact on our company, first of all, we think it is a very good thing to improve access to people who are suffering in this way. As for the impact on our company, it is unclear at this point since the details of the system are still undecided, but our expectation is that by improving access to this kind of infertility treatment , we can contribute to more people who are suffering. Through this, we hope to improve the performance of our company. That's all.

Moderator: Thank you very much. Now, I would like to introduce the next question.

“Please give an overview and details of the prescription-designated dietary supplements. What diseases are they being developed for, when are they expected to be released, and what is the size of the market?”

Iwai: Thank you very much. I will pass this to Mr. Mitsuhashi. Thank you.

Mitsuhashi: Thank you for your question. As I mentioned earlier, this is our first attempt at a prescription supplement, and we are very excited about it. The market size of prescription dietary supplements is approximately JPY20 billion. The market has grown by about 10% in the past 2 years, and is a promising market.

Most of the prescription supplements market is dominated by supplements that directly address women's concerns, which account for a very large percentage of the market. During the period of this Mid-term

Business Plan, we are planning to develop the product as a unified brand and envision 2 dietary supplements in the female domain.

The first is a product for women who wish to have a baby. The other will be a supplement for women with menopause. As for the launch date, we are working to launch the first product in the fiscal year ending September 2022. Thank you.

Moderator: Thank you very much. Now, I would like to introduce the next question.

"Please tell us about the implementation plan and status of the marketing authorization check instructed by the Japan Generic Pharmaceutical Association, as well as the method and timing of its publication."

Iwai: Thank you very much. I think this is a very important question to ensure the safety of pharmaceutical products. Mr. Sato will explain the current situation with respect to this.

Sato: Thank you. I would like to answer your question. We are currently in the process of checking the marketing authorization document. The details will be announced on our website as soon as they are ready.

As for when that will be, I would like to digress for a moment to say that our company's board of directors is composed of 60% outside directors and 50% independent directors. I think this topic is very important for the company, so we are preparing to hold a thorough briefing for the board of directors first. After that, we plan to announce the structure in a way that will commit the Board of Directors to it, so I cannot say anything about the specific timing right now. We are planning to announce it as soon as possible. That's all.

Moderator: Thank you very much. Now, I would like to introduce the next question.

"Please explain the reason why oral contraceptive drugs and emergency contraceptive drugs did not meet the sales plan."

Iwai: I would like to explain about this. In terms of progress, sales are at 45% of the forecast full-year figure at the end of the first half of the fiscal year. That could be read as a failure to meet the plan, but compared to last year's results, we have increased by about 30% in the first half. Therefore, although there is no doubt that demand is growing, the progress has been slightly insufficient, and there has been no further change in the market environment or the growth environment. That's all.

Moderator: Thank you very much. Now, I would like to introduce the next question.

"Has the expansion of subsidies for infertility treatment that started in January 2021 had any impact on business performance?"

Iwai: Another question for Mr. Sato.

Sato: Thank you. To put it briefly, we have seen a positive impact on our business performance. The subsidies were expanded in January, but it took a little time for the subsidies to penetrate into the field, so there was no immediate impact on our business performance. However, we are starting to see an effect.

As for infertility treatments, I have explained the trends in the first half of this report on page 11, so please take a look at that as well. There was also the impact of the coronavirus pandemic, so it is difficult to talk about the market or the sales trends of our drugs based solely on the impact of the subsidies. However, I think we can see that the market is expanding. Thank you.

Moderator: Thank you very much. The next question will be the last one as we are approaching the end of the session. It is as follows.

“Regarding FSN-013, why are the indications different between Japan and ASEAN?”

Iwai: I would like to answer this question. First of all, in terms of the development by Mithra Pharmaceuticals, our licensor, the company is currently in the process of submitting applications for approval as a new oral contraceptive drugs in both Europe and the United States.

On the other hand, our Company has experience with Lunabell in Japan as dysmenorrhea treatments drugs. In order to further meet the needs of patients and medical institutions in the LEP market, we have chosen to develop it as a treatment for dysmenorrhea.

On the other hand, in the ASEAN region, there is a rule that if a product has been submitted for approval in Europe or the United States, the approval data can be used for the application. Therefore, in ASEAN, mainly in Thailand, we will be applying for approval as an oral contraceptive drugs in the same way as Mithra, the licensor.

The reason for the different indications is that, as I mentioned earlier, we have chosen to focus on dysmenorrhea in Japan. That's all.

Moderator: Thank you all for taking the time to ask your questions. I would like to conclude with a few words from President Iwai.

Iwai: Thank you very much for joining us today for our financial results briefing for the second quarter of the fiscal year ending September 30, 2021. We hope you will take a look at our website as well as our presentation materials. Thank you very much for your time today.

Moderator: This concludes the presentation of Fuji Pharma Co. Ltd.'s financial results for the second quarter of the fiscal year ending September 30, 2021. Thank you to everyone who participated.

[END]

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Document Notes

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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.*

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