Fuji Pharma Co., Ltd.

FY9/2023 2Q Investor Meeting

May 19, 2023

Event Summary

[Company Name]	Fuji Pharma Co., Ltd.
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[Participants]	
[Number of Speakers]	3

Takayuki Iwai	President and CEO
Takeshi Sato	Executive Corporate Officer, Corporate Strategy Div. Head of Corporate Planning
Masayuki Naganawa	Corporate Officer, Vice General Manager of Research and Development Department

Presentation

Moderator: Good morning, ladies and gentlemen. Thank you very much for attending today's Financial Results Meeting for Fuji Pharma Co., Ltd.'s Second Quarter of the Fiscal Year ending September 30, 2023.

First of all, I would like to introduce today's attendees. Mr. Takayuki Iwai, President and CEO.

Iwai: Thank you very much.

Moderator: Mr. Takeshi Sato, Executive Corporate Officer, Corporate Strategy Div. Head of Corporate Planning

Sato: Thank you very much.

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

Naganawa: Thank you very much.

Moderator: Now, to proceed with today's proceedings.

I would like to ask Executive Corporate Officer, Sato, to give an overview of the consolidated financial results for Q2 of the fiscal year ending September 30, 2023, and President Iwai to explain the progress of the Medium-Term Business Plan, women's healthcare, and today's summary; and Corporate Officer Naganawa to explain the clinical trial status of FSN-013.

We will then proceed to the question and answer session. We would like to receive as many questions as time permits, so please do not hesitate to ask us any questions you may have. We will be happy to receive your questions via chat with you at any time during the presentation.

I will now move on to the explanation.

President Iwai, please begin.

Iwai: Yes, thank you all very much for taking time out of your busy schedules today to participate in the financial results briefing for Q2 of the fiscal year ending September 30, 2023, of Fuji Pharma Co., Ltd.

Today, I would like to explain three agendas.

I would like to begin with a summary of the consolidated financial results in the first section, followed by the progress of the Medium-Term Business Plan in the second section, and finally, an overall summary. We would appreciate it if you stayed with us until the end.

Now, let me begin with the presentation. Mr. Sato, Executive Corporate Officer, will give an overview of the consolidated financial results for Q2 of the fiscal year ending September 30, 2023.

FY9/23 2Q Financial Result Highlights

- **Net sales increased due to existing/new products in Women's Healthcare**
  - Net Sales: +8.5% YoY due to increase of Women's Healthcare products
  - Profit: ▲32.7% YoY due to increase in raw materials, amortization of intangible assets, and R&D expenses
  - OLIC: Net sales +40.1% YoY due to increase in new contracts and a weaker JPY against THB

- **Research and Development-Related Topics**
  - FSN-013: Phase III study completed
  - Biosimilars: One product submitted for approval and under review

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Sato: My name is Sato from the Corporate Planning Department. Thank you for joining us today.

I would like to provide an overview of the consolidated financial results for Q2 of the fiscal year ending September 30, 2023.

In H1 of the fiscal year ending September 30, 2023, sales increased due to contributions from existing and then new products in the women's healthcare area. On the other hand, operating profit decreased due to higher raw material costs, the start of amortization of intangible assets, and higher R&D expenses.

OLIC, a subsidiary in Thailand, reported a YoY increase in revenue due to new contracts and other factors.

Topics in H1 of the year in R&D-related were the completion of the Phase III study for FSN-013 and in progress for the preparation of an approved application. Also, we applied for approval of the first biosimilar through our partnership with Alvotech.

Summary of FY9/23 2Q Consolidated Financial Results

- Net sales: +1,499 million yen (+8.5% YoY) due to growth in Women's Healthcare
- Operating Profit: ▲888 million yen (▲32.7% YoY) due to higher API costs, amortization of intangibles, and R&D expenses
- Profit Attributable to Owners of Parent: ▲62 million yen (▲3.3% YoY) due to derivatives related to stockholdings, etc.

(¥million)	FY9/22 First half	FY9/23 First half	YoY Change Amount	YoY Change Ratio	FY9/23 First half Forecast	vs Fcst Achievement Ratio	FY9/23 Forecast	vs Fcst Progress Ratio
Net Sales	17,726	**19,225**	1,499	8.5%	**20,144**	95.4%	**43,311**	44.4%
Gross Profit	7,675	**7,623**	▲ 52	-0.7%	-	-	-	-
Gross Margin	43.3%	**39.7%**	-	-	-	-	-	-
SG&A Expenses	4,963	**5,799**	836	16.8%	-	-	-	-
SG&A Margin	28.0%	**30.2%**	-	-	-	-	-	-
Operating Profit	2,712	**1,824**	▲ 888	-32.7%	**2,003**	91.1%	**4,048**	45.1%
Operating Margin	15.3%	**9.5%**	-	-	**9.9%**		**9.3%**	-
Ordinary Profit	2,866	**2,456**	▲ 410	-14.3%	**2,023**	121.4%	**4,088**	60.1%
Ordinary Margin	16.2%	**12.8%**	-	-	**10.0%**		**9.4%**	-
Profit Attributable to Owners of Parent	1,834	**1,772**	▲ 62	-3.3%	**1,476**	120.1%	**2,974**	59.6%
Profit Margin	10.3%	**9.2%**	-	-	**7.3%**		**6.9%**	-
EBITDAR*1	4,974	**4,418**	▲ 556	-11.2%			**10,975**	40.3%
EBITDA*2	3,822	**3,050**	▲ 772	-20.2%			**7,137**	42.7%
Capital Expenditure	3,449	**1,088**	▲ 2,361	-68.5%			**5,715**	19.0%
Depreciation (Including Leased Equipmen	1,109	**1,226**	117	10.6%			**3,089**	39.7%
R&D Expenses	1,152	**1,368**	216	18.8%			**3,838**	35.6%
R&D Expenses Ratio	6.5%	**7.1%**	-	-			**8.9%**	-

*1) EBITDAR : Gross Profit－SG&A Expenses＋Depretiation (Including Leased Equipment)＋R&D Expenses
*2) EBITDA : Gross Profit－SG&A Expenses＋Depretiation (Including Leased Equipment)

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As an overview of the financial results, we are planning full-year sales of JPY43.3 billion for the current fiscal year. We had planned to exceed JPY20 billion in H1 of the year, but as a result, sales fell short by about 5% to JPY19.2 billion.

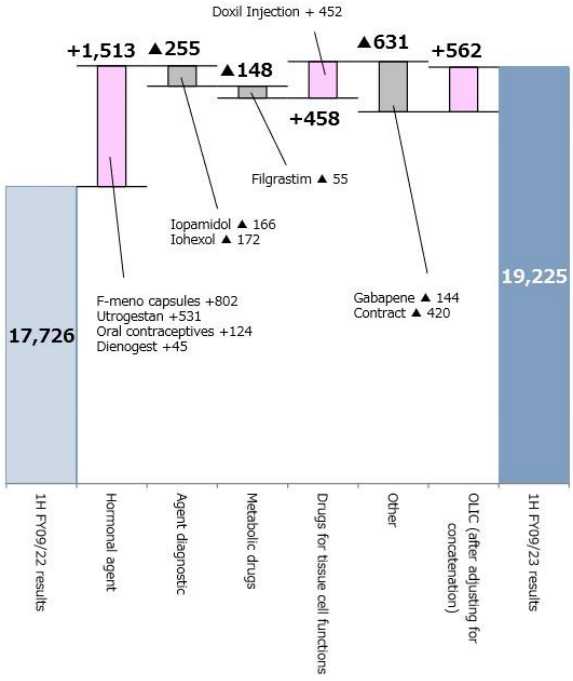
Operating profit was 33% lower than the previous year and 9% lower than the budget. The reasons will be explained in the next slide.

The half-yearly progress rate of net sales and operating profit is approximately 45% each, and we will make every effort to achieve the full-year forecast in H2 of the fiscal year.

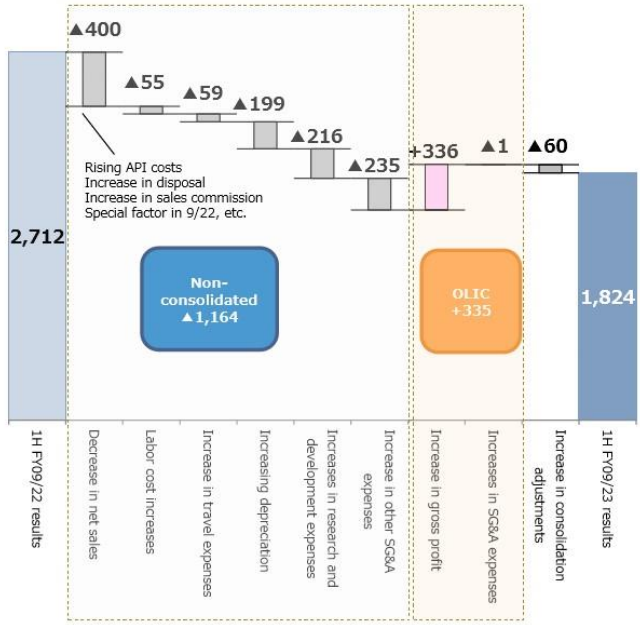
Due to non-operating items, such as a gain on the valuation of derivatives of Alvotech's classified stock, ordinary profit, and net income were lower than the previous year, but exceeded the budget.

Summary of FY9/23 2Q Consolidated Financial Results (YoY)

Net sales (Unit:¥million)



Operating Profit (Unit:¥million)



*1) Change in brand name: Iopamidol (old name: Oypalomine ® Note), Iohexol (old name: Iopark ® Note)
*2) OLIC: Our subsidiary. A CMO company that owns a Thai headquarters and plant

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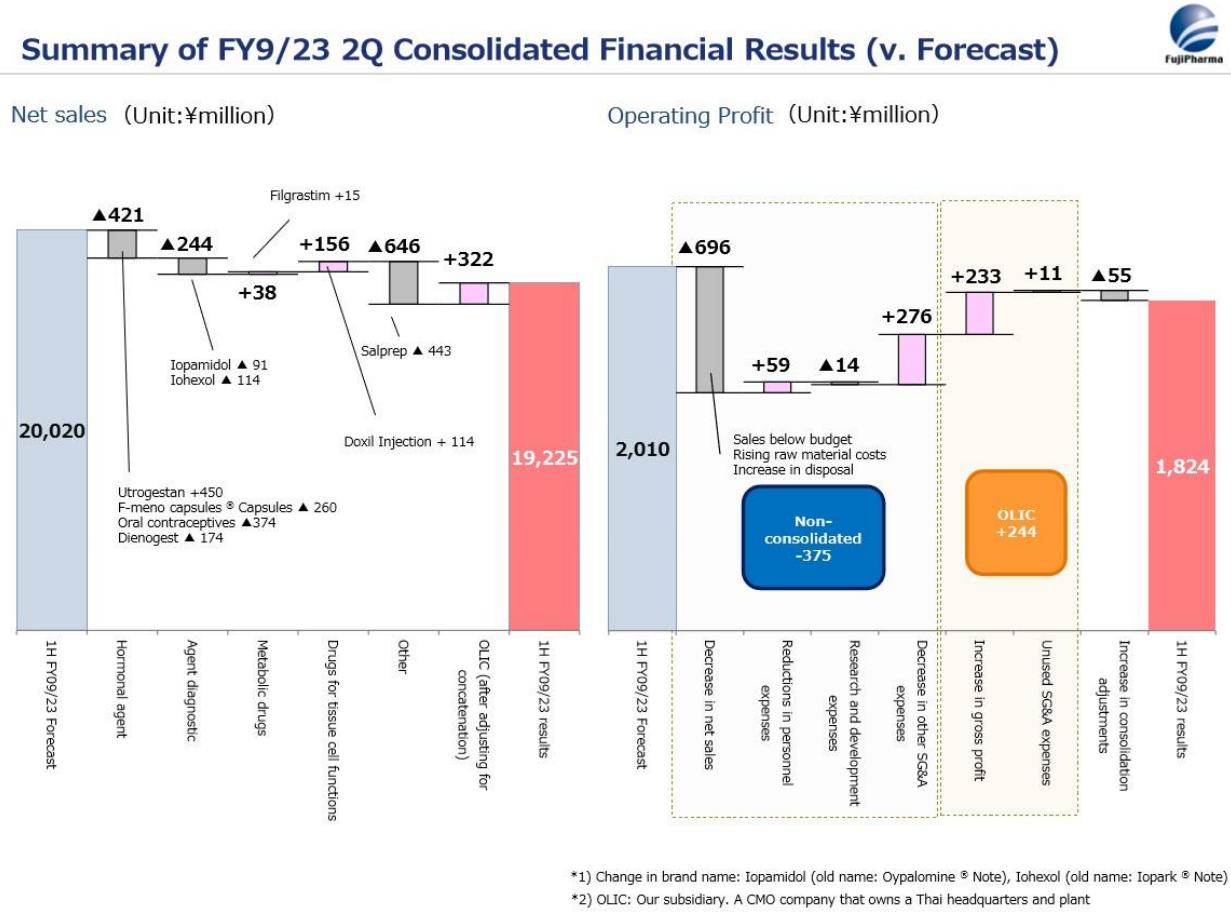
Here is an analysis of the difference between net sales and operating profit compared to the previous year.

In terms of sales, hormone drugs, mainly in the area of women's healthcare, and cellular function affecting drugs grew significantly. The contribution of OLIC also made up for the decline in diagnostic drugs and other drugs.

On the other hand, the overall downward pressure on gross profit was about JPY700 million, due to soaring raw material costs, increased disposal, increased sales commissions, and special cost reduction factors in the previous period but not in the current period.

As a result, gross profit decreased by JPY400 million. Other SG&A expenses increased in line with the increase in sales, and R&D expenses also increased, resulting in a consolidated decrease in profit despite a large increase in OLIC.

Summary of FY9/23 2Q Consolidated Financial Results (v. Forecast)



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Next, I will explain the analysis of the difference between net sales and operating profit compared to the forecast.

Net sales fell about 5% short of the forecast due to the slower-than-expected launch of F-meno and SULPREP, new additions to the portfolio, as well as the failure of the supply of oral contraceptives to keep pace with the market.

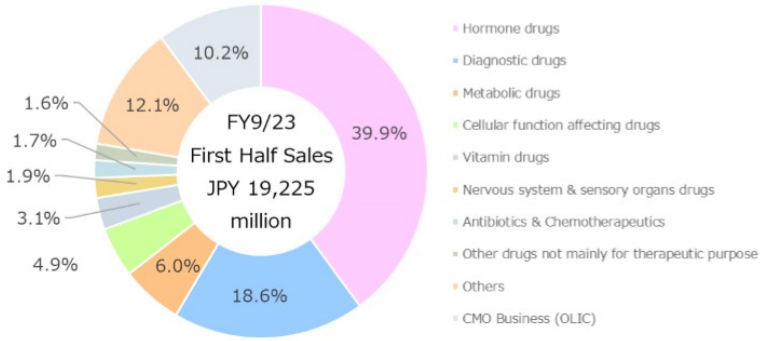
Operating profit fell short of the forecast by about 9% due to the underachievement of sales and a large decrease in gross profit, caused by soaring raw material prices and an increase in waste disposal, as I mentioned earlier, even though we have made efforts to reduce SG&A expenses compared to the budget, and OLIC also exceeded the budget.

Sales by Therapeutic Category

(¥million)	FY9/19 First half Old accounting standards	FY9/20 First half Old accounting standards	FY9/21 First half Old accounting standards	FY9/22 First half New accounting standards	**FY9/23 First half New accounting standards**	YoY Change Amount	YoY Change Ratio
Hormone drugs	5,278	5,053	5,707	6,158	**7,671**	1,513	24.6%
Diagnostic drugs	6,028	4,456	4,315	3,831	**3,576**	▲ 255	-6.7%
Metabolic drugs	1,505	1,572	1,640	1,299	**1,151**	▲ 148	-11.4%
Cellular function affecting drugs	461	476	491	476	**934**	458	96.2%
Vitamin drugs	206	180	197	499	**592**	93	18.6%
Nervous system & sensory organs drugs	449	593	593	515	**372**	▲ 143	-27.8%
Antibiotics & Chemotherapeutics	397	368	278	295	**329**	34	11.5%
Other drugs not mainly for therapeutic purpose	-	-	-	296	**305**	9	3.0%
Others	2,970	2,913	2,902	2,948	**2,327**	▲ 621	-21.1%
Of which, CMO Business (FUJI)	*1,126*	*1,269*	*1,501*	*1,863*	***1,443***	*▲ 420*	*-22.5%*
CMO Business (OLIC)	1,186	1,290	1,149	1,403	**1,965**	562	40.1%
Total	18,483	16,905	17,277	17,726	**19,225**	1,499	8.5%

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

Sales Breakdown by Therapeutic Category



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Continuing on, the sales by therapeutic category are as shown on the slide that you are now seeing.

Hormone drugs, mainly in the area of women's health, grew significantly, accounting for about 40% of net sales. As for consignment, the Toyama factory had a negative impact due to a delay at the start of the production period.

On the other hand, OLIC is positive, which means that there was a slight increase overall. This accounts for approximately 20% of net sales.

Sales of Top 15 Products

Product Name (¥million)	Therapeutic Category	FY9/19 First half Old accounting standards	FY9/20 First half Old accounting standards	FY9/21 First half Old accounting standards	FY9/22 First half New accounting standards	**FY9/23 First half New accounting standards**	YoY Change Amount	YoY Change Ratio	FY9/23 Forecast	FY9/23 Progress Ratio
★IOPAMIDOL injection	Diagnostic drugs	3,580	3,342	3,206	3,057	**2,891**	▲ 166	-5.4%	6,496	44.5%
◆UTROGESTAN® vaginal capsules	Hormone drugs	332	350	442	582	**1,113**	531	91.2%	1,396	79.7%
F-meno® capsules	Hormone drugs	-	-	-	117	**918**	801	684.6%	3,500	26.2%
DIENOGEST tablets	Hormone drugs	532	596	830	812	**857**	45	5.5%	2,082	41.2%
Favoir® tablets	Hormone drugs	328	464	601	749	**834**	85	11.3%	2,215	37.7%
Filgrastim BS Injection Syringe	Metabolic drugs	945	1,097	1,212	880	**825**	▲ 55	-6.3%	1,665	49.5%
★IOHEXOL injection	Diagnostic drugs	1,115	1,116	1,109	896	**724**	▲ 172	-19.2%	1,719	42.1%
Labellefille® tablets	Hormone drugs	316	393	497	500	**539**	39	7.8%	1,769	30.5%
DOXIL® Injection	Cellular function affecting drugs	-	-	-	-	**451**	-	-	1,408	32.0%
DEXART® injection	Hormone drugs	435	435	445	418	**441**	23	5.5%	835	52.8%
LEVONORGESTREL tablets	Hormone drugs	47	326	370	447	**433**	▲ 14	-3.1%	1,199	36.1%
BUSERELIN nasal solution	Hormone drugs	218	202	216	252	**416**	164	65.1%	627	66.3%
LUNABELL® tablets (LD/ULD)	Hormone drugs	978	534	472	470	**403**	▲ 67	-14.3%	872	46.2%
FOLIAMIN® TABLETS/POWDER/INJECTION	Vitamin drugs	-	-	-	304	**403**	99	32.6%	823	49.0%
GABAPEN® Tablets/Syrup	Nervous system & sensory organs drugs	-	543	538	497	**353**	▲ 144	-29.0%	725	48.7%
Total Top 15 Sales		8,826	9,400	9,943	9,987	**11,609**	1,622	16.2%	27,335	42.5%
Pct. Of Total Sales		48.7%	53.9%	57.6%	56.3%	60.4%			63.1%	
Other Products		8,103	6,757	6,183	6,335	**5,650**	▲ 685	-10.8%	12,565	45.0%
CMO Business (OLIC)		1,186	1,290	1,149	1,403	**1,965**	562	40.1%	3,410	57.6%
Total		18,115	17,448	17,277	17,726	**19,225**	1,499	8.5%	43,311	44.4%
[Reference]Branded contrast media		1,245	-	-	-	-				

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

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The following shows the sales figures for the top 15 products.

Although the progress rate for some products, such as UTROGESTAN, exceeded 50%, the rate for F-meno, oral contraceptives, contrast agents, and other products was at or below the 40% level, which was not encouraging.

Iwai will explain the status of F-meno and oral contraceptives in H1 of the year and our efforts in the H2, along with other major formulations in the area of women's healthcare, later.

In addition, SUPREP, which was included in the top 15 products in our full-year forecast, did not grow as much as expected in H1 of the year and was omitted from this list of 15 products.

As for SUPREP, we are working to achieve our initial plan in the medium term, and the status is described in the appendix of this document.

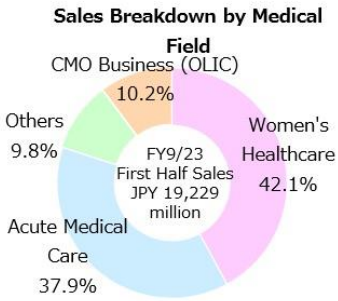
Sales by Medical Field and Drug Form Category

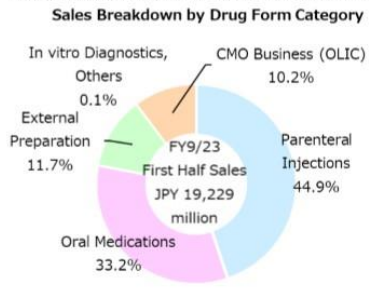
Medical Field Category (¥million)	FY9/19 First half Old accounting standards	FY9/20 First half Old accounting standards	FY9/21 First half Old accounting standards	FY9/22 First half New accounting standards	**FY9/23 First half New accounting standards**	YoY Change Amount	YoY Change Ratio
Women's Healthcare	5,154	5,316	5,896	6,384	**8,091**	1,707	26.7%
Acute Medical Care	10,346	8,414	8,584	7,989	**7,284**	▲ 705	-8.8%
Others	1,795	1,884	1,646	1,949	**1,884**	▲ 65	-3.3%
CMO Business (OLIC)	1,186	1,290	1,149	1,403	**1,965**	562	40.1%
Total	18,483	16,905	17,277	17,726	**19,225**	1,499	8.5%

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

Drug Form Category (¥million)	FY9/19 First half Old accounting standards	FY9/20 First half Old accounting standards	FY9/21 First half Old accounting standards	FY9/22 First half New accounting standards	**FY9/23 First half New accounting standards**	YoY Change Amount	YoY Change Ratio
Parenteral Injections	10,998	9,157	9,362	8,777	**8,625**	▲ 152	-1.7%
Oral Medications	4,615	4,796	5,065	5,299	**6,377**	1,078	20.3%
External Preparation	1,238	1,251	1,383	1,545	**2,245**	700	45.3%
In vitro Diagnostics, Others	445	409	316	700	**12**	▲ 688	-98.3%
CMO Business (OLIC)	1,186	1,290	1,149	1,403	**1,965**	562	40.1%
Total	18,483	16,905	17,277	17,726	**19,225**	1,499	8.5%

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





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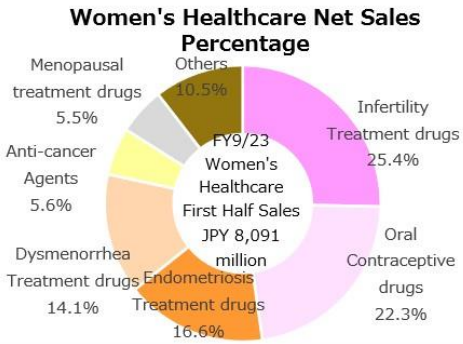
Sales by medical field and drug form category are shown in the table below.

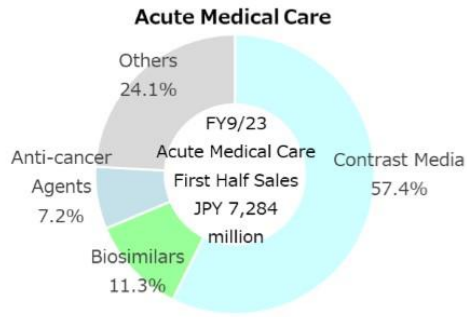
This area had the largest percentage of acute medical care in H1 of the previous fiscal year, but it has the largest percentage in the area of women's healthcare this fiscal year.

Sales of Acute Medical Care and Women's Healthcare

Women's Healthcare (¥Million)	FY9/19 First half Old accounting standards	FY9/20 First half Old accounting standards	FY9/21 First half Old accounting standards	FY9/22 First half New accounting standards	**FY9/23 First half New accounting standards**	YoY Change Amount	YoY Change Ratio
Infertility Treatment drugs	1,475	1,411	1,553	1,650	**2,052**	402	24.4%
Oral Contraceptive drugs	644	1,183	1,469	1,697	**1,807**	110	6.5%
Endometriosis Treatment drugs	915	1,012	1,255	1,211	**1,340**	129	10.7%
Dysmenorrhea Treatment drugs	154	167	185	328	**1,141**	813	247.9%
Anti-cancer Agents	-	-	-	-	**451**	-	-
Menopausal treatment drugs	1,030	602	524	519	**447**	▲ 72	-13.9%
Others	933	937	908	976	**849**	▲ 127	-13.0%
Total	5,154	5,316	5,896	6,384	**8,091**	1,707	26.7%

Acute Medical Care (¥Million)	FY9/19 First half Old accounting standards	FY9/20 First half Old accounting standards	FY9/21 First half Old accounting standards	FY9/22 First half New accounting standards	**FY9/23 First half New accounting standards**	YoY Change Amount	YoY Change Ratio
Contrast Media	6,661	4,796	4,718	4,364	**4,176**	▲ 188	-4.3%
Biosimilars	945	1,097	1,212	880	**825**	▲ 55	-6.3%
Anti-cancer Agents	410	457	597	706	**524**	▲ 182	-25.8%
Others	2,329	2,062	2,056	2,037	**1,756**	▲ 281	-13.8%
Total	10,346	8,414	8,584	7,989	**7,284**	▲ 705	-8.8%





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This is followed by a description of the changes in sales for women's healthcare and acute care.

The composition ratio of menopausal drugs has increased from 5% in H1 of the previous fiscal year to 14% in the current fiscal year.

FY9/23 2Q Summary of Consolidated Balance Sheet

(¥million)	FY9/21 Year End	**FY9/22 End of 2Q**	YoY Change Amount	YoY Change Ratio
Assets				
Current Assets	34,727	**38,925**	4,198	12.1%
Cash and Deposits	3,546	**5,282**	1,735	49.0%
Notes and Accounts Receivable - Trade	12,528	**14,229**	1,701	13.6%
Inventories	15,824	**17,773**	1,949	12.3%
Other	2,828	**1,641**	▲ 1,187	-42.0%
Non-current Assests	40,810	**45,877**	5,067	12.4%
Property, Plant and Equipment	18,762	**18,998**	235	1.3%
Intangible Assets	10,404	**10,123**	▲ 281	-2.7%
Investments and Other Assets	11,643	**16,755**	5,112	43.9%
Total Assets	75,538	**84,803**	9,265	12.3%
Liabilities				
Current Liabilities	23,975	**25,582**	1,606	6.7%
Notes and Accounts Payable - Trade	6,249	**7,083**	834	13.3%
	8,300	**10,300**	2,000	24.1%
	2,440	**2,320**	▲ 120	-4.9%
	-	**600**	600	-
Other	6,986	**5,278**	▲ 1,707	-24.4%
Non-current Liabilities	15,756	**18,769**	3,012	19.1%
	11,193	**10,093**	▲ 1,100	-9.8%
	-	**2,400**	2,400	-
	4,562	**6,275**	1,712	37.5%
Total Liabilities	39,732	**44,351**	4,619	11.6%
Net Assets				
Share capital	34,175	**35,473**	1,297	3.8%
Capital Stock	3,799	**3,799**	-	0.0%
Capital Surplus	4,409	**4,409**	-	0.0%
Retained Earnings	26,546	**27,832**	1,286	4.8%
Treasury Shares	▲ 579	**▲ 567**	11	-2.1%
Accumulated Other Comprehensive income	1,627	**4,975**	3,347	205.8%
Total Net Assets	35,806	**40,452**	4,646	13.0%
Total Liabilites and Net Assets	75,538	**84,803**	9,265	12.3%

Increase in Net sales

For stable supply
Increase API

Alvotech, Lotus stock
Increase due to market valuation

ESG privately placed bonds

Alvotech, Lotus stock
Increase due to market valuation

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Continued, here is the balance sheet information.

Assets and liabilities related to working capital have increased in line with the increase in sales.

There is an increase in bulk chemicals to ensure a stable supply in regard to the working capital.

In addition, there was an increase in the valuation of shares in Alvotech and Lotus, both listed stocks held in investments.

The bonds recorded in the current period are ESG-related private placement bonds.

Although I mentioned that the shares of Alvotech and Lotus are listed shares, they are both parties with whom we have entered into business and capital alliances and are, therefore, distinct from general policy shareholdings.

FY9/23 2Q Summary of Consolidated Statements of Cash Flows

(¥million)	FY9/22 First half	**FY9/23 First half**	YoY Change Amount	YoY Change Ratio
Cash Flows from Operating Activities	▲ 1,076	**1,516**	2,592	-240.9%
(Major Breakdown)				
Profit Before Income Taxes	2,865	**2,456**	▲ 409	-14.3%
Depreciation	1,100	**1,294**	194	17.6%
Amortization of Goodwill	138	**157**	19	13.8%
Decrease (increase) in trade receivables	▲ 441	**▲ 1,674**	▲ 1,233	279.6%
Decrease (Increase) in Inventories	▲ 1,270	**▲ 1,896**	▲ 626	49.3%
Increase (decrease) in trade payables	▲ 422	**807**	1,229	-291.2%
Income Taxes Paid	▲ 739	**▲ 551**	188	-25.4%
Cash Flows from Investing Activities	▲ 10,296	**▲ 2,872**	7,424	-72.1%
(Major Breakdown)				
Purchase of Property, Plant and Equipment	▲ 2,977	**▲ 1,248**	1,729	-58.1%
Purchase of Intangible Assets	▲ 7,092	**▲ 276**	6,816	-96.1%
	▲ 230	**▲ 1,242**	▲ 1,012	440.0%
Cash Flows from Financing Activities	6,988	**3,058**	▲ 3,930	-
(Major Breakdown)				
Net increase (decrease) in Short-Term Loans Payable	1,300	**2,000**	700	53.8%
Proceeds from Long-Term Loans Payable	7,300	**0**	▲ 7,300	-100.0%
Repayments of Long-Term Loans Payable	▲ 920	**▲ 1,220**	▲ 300	32.6%
Dividends paid	▲ 364	**▲ 486**	▲ 122	33.5%
Repayments of Lease Obligations	▲ 326	**▲ 221**	105	-32.2%
Cash and Cash Equivalents at Beginning of Period	10,199	**3,546**	▲ 6,653	-65.2%
Cash and Cash Equivalents at End of Period	5,975	**5,282**	▲ 693	-11.6%
Free Cash Flows	▲ 11,372	**▲ 1,355**	10,017	-88.1%

Net sales increase, W/C has increased as well.

In FY9 / 22 2Q, marketing rights were obtained

In FY9 / 22 2Q,borrowing Use of marketing rights

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Continuing on to cash flow, we see the same trend as on the balance sheet in terms of operating cash flow, with working capital increasing in line with the increase in sales.

In terms of investment cash flow, there was a large decrease due to the acquisition of sales rights in the previous year, and the fact that capital investment at the plant has settled down.

FY9/23 Consolidated Forecast

- Net sales and Operating Profit reached 45% in 1H
  FY9/23 Consolidated Forecast remain unchanged due to strengthening of sales activities and cost control in the 2H

(¥million)	FY9/21 Actual	FY9/22 Actual	**FY9/23 Forecast**	YoY Change (New accounting standards)		**FY9/23 First half actual**	**FY9/23 Second half forecast**
				Amount	Ratio		
Net Sales	32,645	35,966	**43,311**	7,345	20.4%	19,225	24,086
Operating Profit	3,349	3,490	**4,048**	558	16.0%	1,824	2,224
Operating Margin	10.3%	9.7%	**9.3%**	-	-	9.5%	9.2%
Ordinary Profit	3,250	3,540	**4,088**	548	15.5%	2,456	1,632
Ordinary Margin	10.0%	9.8%	**9.4%**	-	-	12.8%	6.8%
Profit Attributable to Owners of Parent	2,432	2,562	**2,974**	412	16.1%	1,772	1,202
Profit Margin	7.4%	7.1%	**6.9%**	-	-	9.2%	5.0%
ROIC＊1	8.2%	6.7%	**7.4%**				
WACC			**5.0%**				
EBITDAR＊2	7,688	8,059	**10,975**	2,916	36.2%	4,418	6,557
EBITDA＊3	5,242	5,250	**7,137**	1,887	35.9%	3,050	4,087
Capital Expenditure	3,392	7,172	**5,715**	▲ 1,457	-20.3%	1,088	4,627
Depreciation (Inclusind Leased Equipment)	1,893	1,760	**3,089**	1,329	75.5%	1,226	1,863
R&D Expenses	2,446	2,809	**3,838**	1,029	36.6%	1,368	2,470
R&D Expenses Ratio	7.5%	7.8%	**8.9%**	-	-	7.1%	10.3%

＊1) ROIC : Operating Profit / (Equity + Net debt) FY09/23 is Forecast
＊2) EBITDAR : Gross Profit－SG&A Expenses＋Depretiation (Including Leased Equipment)＋R&D Expenses
＊3) EBITDA : Gross Profit－SG&A Expenses＋Depretiation (Including Leased Equipment)

※ The 2H FY9/23 forecast is calculated by subtracting the 1H FY9/23 results from the FY9/23 forecast

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The full-year forecast remains unchanged from the initial forecast.

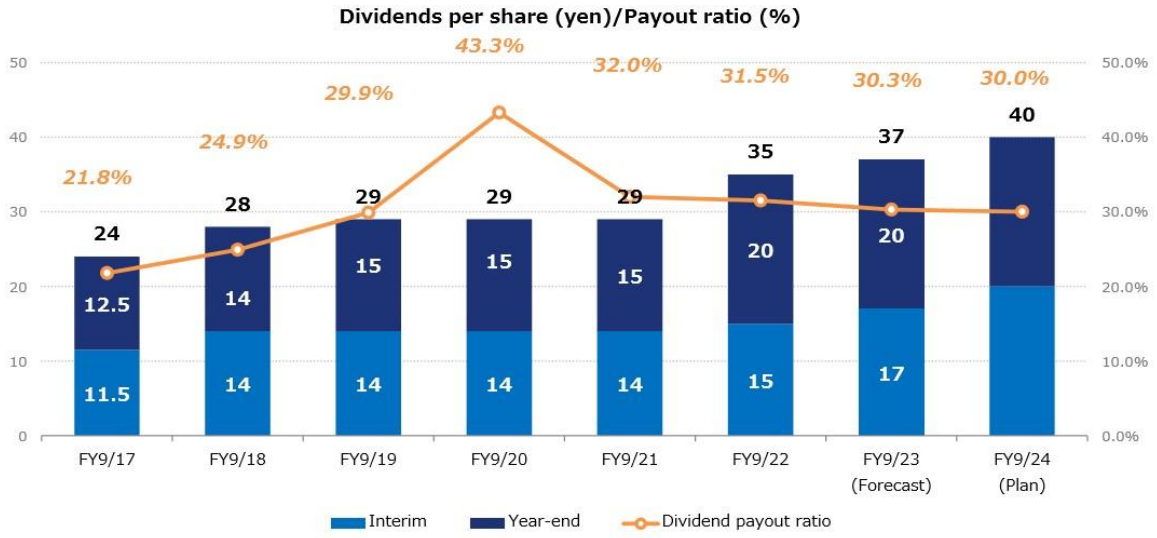
In H1, the progress rate of both net sales and operating income was approximately 45%. We will step up activities to capture the initial forecast in H2 of the fiscal year.

In addition, ROIC and WACC disclosures have been started from this time. This means disclosing figures to start with, and we hope to improve the disclosure through dialogue with investors based on these figures.

We would be happy to receive your comments and suggestions on this matter.

FY9/23 Shareholder Return

- Our dividend policy is to pay a dividend payout ratio of 30%, centered on stable dividends.
- We plan to pay an annual dividend of ¥37 per share (interim dividend of ¥17, year-end dividend of ¥20 per share) by applying a dividend payout ratio of 30% against the forecast for the fiscal year ending FY9/23.



※ Implemented a 2-for-1 stock split on July 1, 2018
Therefore, before the interim dividend for the fiscal year ended September 2018, dividends per share are calculated assuming that the stock split has been executed.
※ Dividend payout ratio for 2023/9 is the initial target

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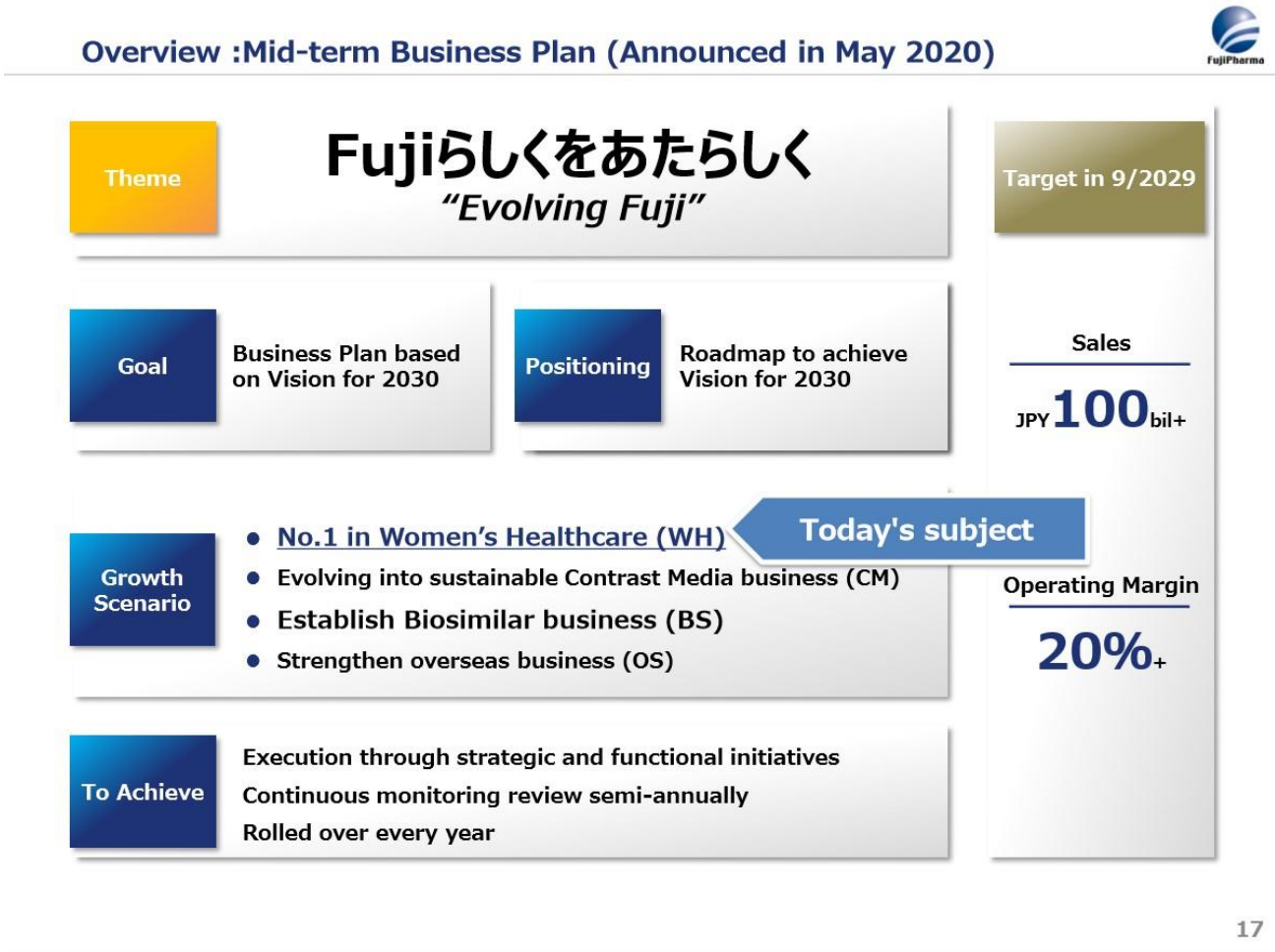
Finally, I would like to discuss shareholder returns for the fiscal year ending September 30, 2023.

Our dividend policy is to aim for a dividend payout ratio of 30% based on stable dividends, which we have explained in the corporate report and other documents.

If profits for the current fiscal year reach the forecasted level, we plan to pay an annual dividend of JPY37 per share, applying a dividend payout ratio of 30%. Based on the H1 results, we have already announced that the interim dividend will be JPY17 per share as planned.

As for the Corporate Report, the new 2023 corporate report is disclosed on the web, in Japanese only. We hope you will also take a look at this page.

That is all I have to say.

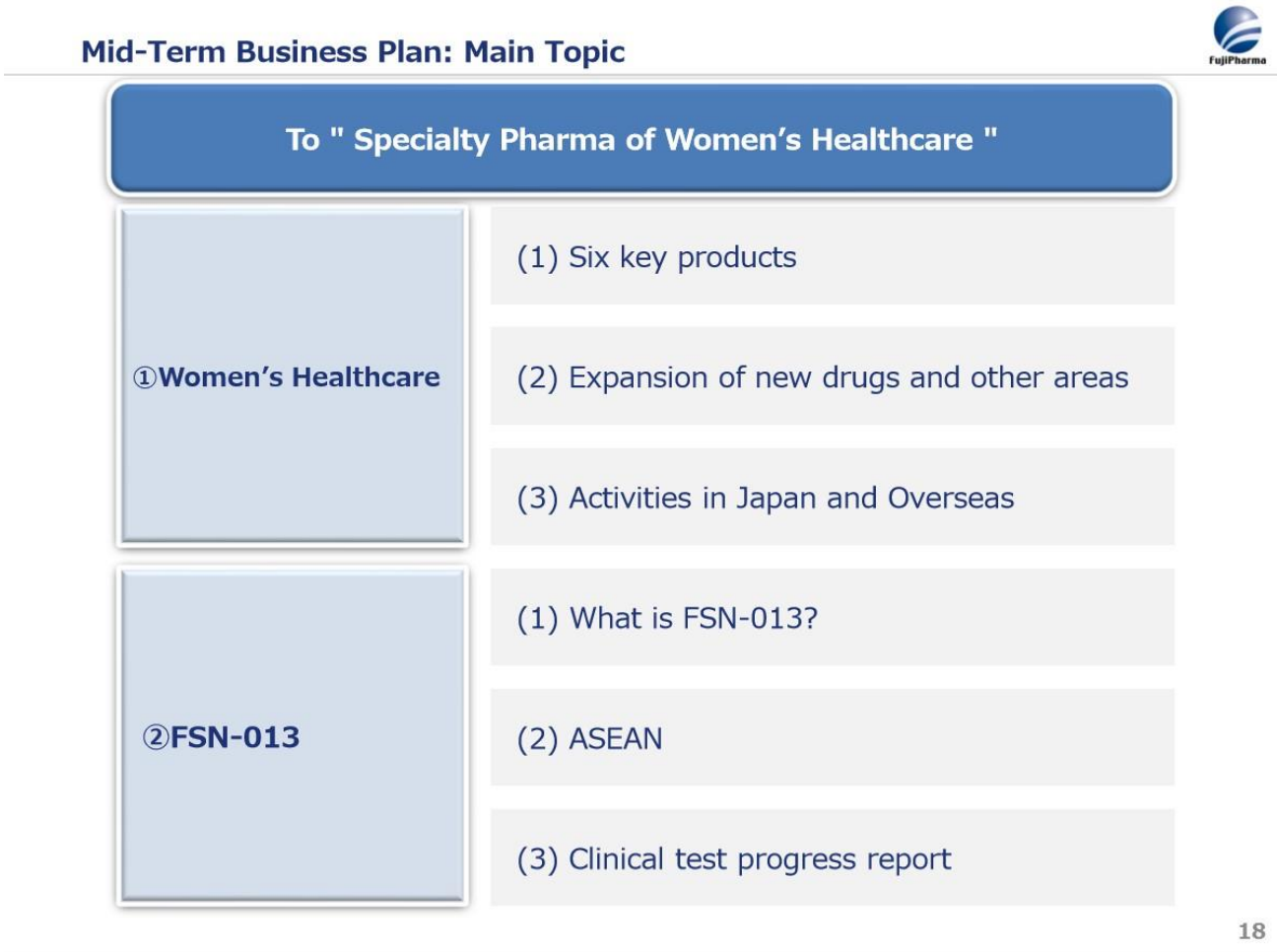


Iwai: Now, I would like to explain chapter two.

I have shown you the four growth scenarios several times, but today I would like to focus on women's healthcare for two reasons.

For the first reason, I mentioned at the last briefing that we will be converting from a so-called generic manufacturer to a specialty pharmaceutical company that specializes in a particular area in the future. We are now making steady progress in becoming a specialty pharma in the women's field, and as Sato explained earlier, the percentage of our sales in the women's healthcare field is now 42%, exceeding 40% for the first time, which is over the acute medical care field.

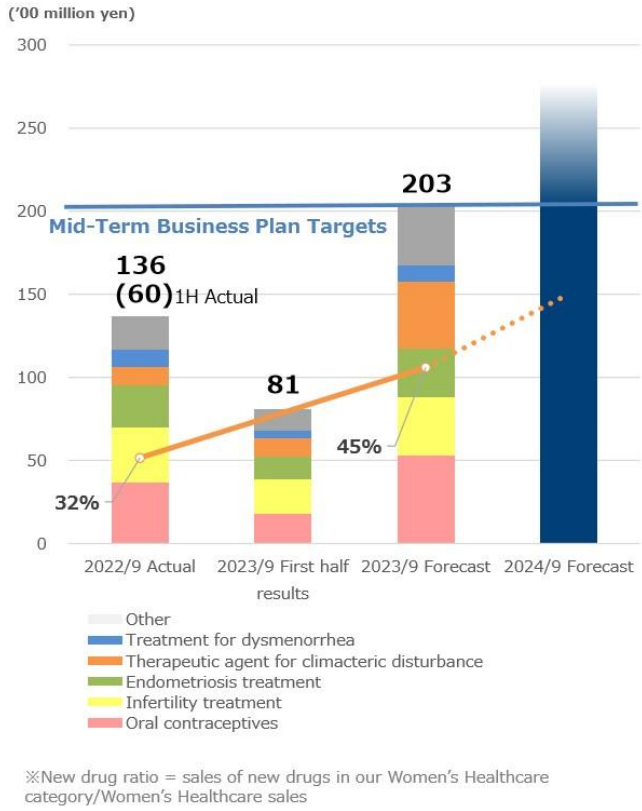
In order to focus more on women, I would like to talk about one of the four scenarios, the top one, which is about women.



As I mentioned earlier, we are currently working to become a specialty pharmaceutical company in the field of women's healthcare.

I would like to give you an overall idea of this field in the next two slides. I will then talk about women's healthcare in Japan in general, including new drugs, and FSN-013, which is currently under development.

To " Specialty Pharma of Women's Healthcare "



※New drug ratio = sales of new drugs in our Women's Healthcare category/Women's Healthcare sales

Activities in Women's Healthcare

①Overall

- ✓ Strengthen and expand product portfolio
- ✓ Pursuing inorganic growth opportunities such as product acquisition
- ✓ Expand playing field
- ✓ Industry and educational activities
- ✓ Overseas expansion

②FSN-013

- ✓ Continue development and prepare for marketing
- ✓ Launch in Thailand, and preparation for expanding into other ASEAN countries

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First of all, as for overall topics, this is a slide from the business plan for this fiscal year. The performance of H1 of this year was added here. When I explained the business plan, I mentioned that the original plan was to achieve sales of JPY20 billion in this field in the next fiscal year, ending September 2024, and that we expect to achieve this plan one year ahead of schedule.

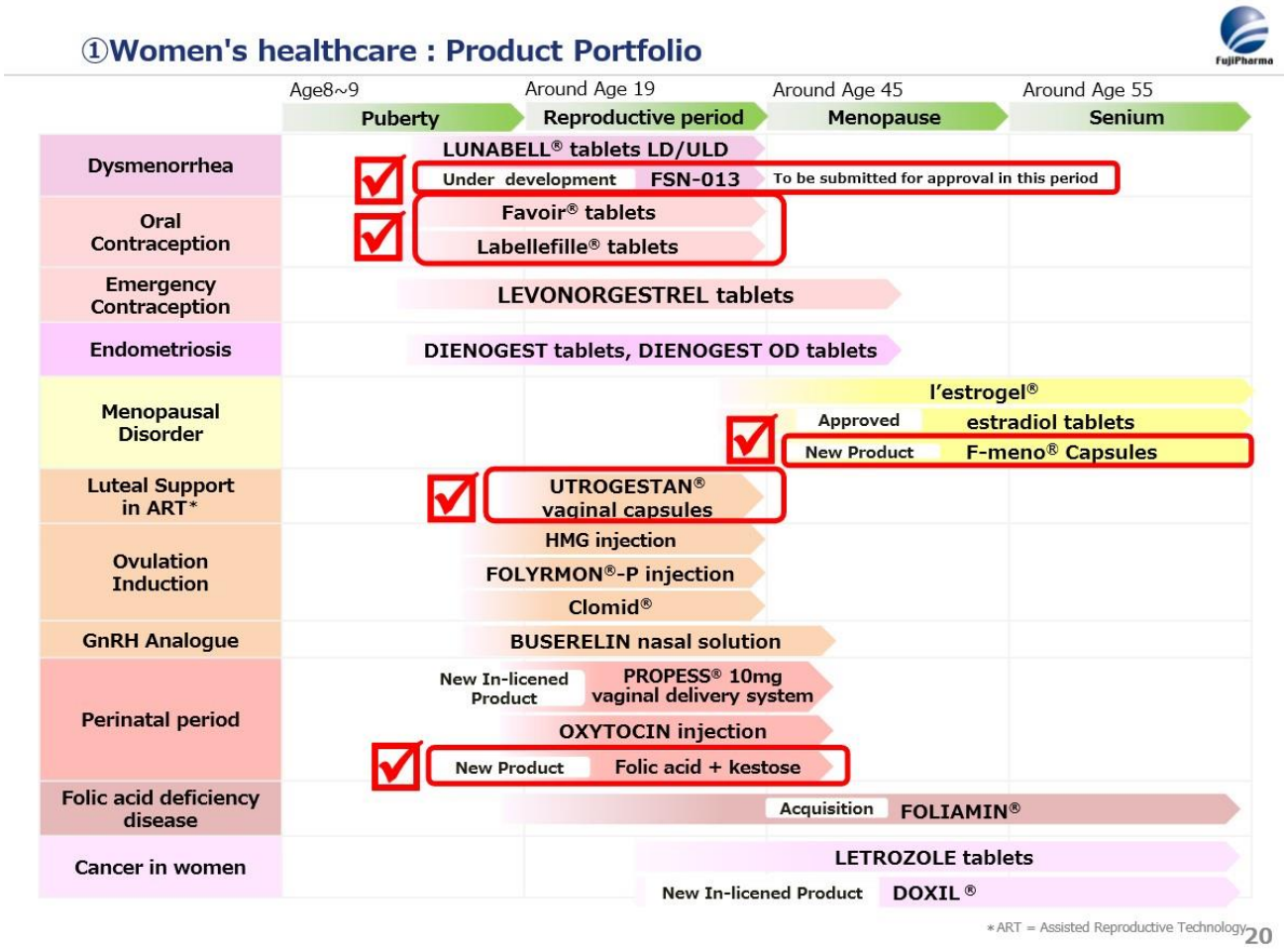
The actual amount for H1 of the current fiscal year was JPY8.1 billion. Compared with JPY6.0 billion for the same period last year, there is an increase of approximately JPY2.0 billion from the same period last year.

On the other hand, although the actual amount achieved 40% of the current fiscal year's plan, this will be in line with our forecast for the full year.

On the right side of the slide, I am showing you now, you can see what we are currently focusing on.

I will talk in more detail on the next slide, but we are currently focusing on strengthening and expanding our portfolio in the area of women's healthcare.

In addition, we are preparing for the submission of the next new drug, FSN-013, in Japan, and are also in the process of starting its marketing in Thailand. These will be explained in more detail later.



Based on this quantitative overall situation, we are currently preparing a product portfolio for a wide range of women's diseases in the field of women's healthcare, from young adults to menopausal and geriatric patients.

We have been explaining the six major products, but we are now moving forward in two directions: first, to deliver these six major products to medical institutions and patients.

Second, to make further contributions to patients by offering new drugs and new products. This is the direction in which we are moving forward.

Today, I would like to talk about the status of our efforts for each product, focusing on the products circled here in red, so that you can understand a little more about our current aim to become a specialty pharma in the women's field.

①Women's Healthcare (1) Six key products

(Unit: '00 million yen, rounded down to 10 million yen)

WH 6 Products	Adaption	Situation	9/2020	9/2021	9/2022	9/2023 (Results for the 1H)	9/2023 (forecast)	9/2024 (Plan)
LEVONORGESTREL (the same)*	Emergency contraception	Market expansion due to launch of generic drugs Maintain +80% volume share	6	8	10	4	11	15
Favoir® (Ethinylestradiol / Desogestrel)*	Contraception	Domestic oral contraceptive market No.1 volume by manufacturer	10	13	16	8	22	27
Labellefille® (Ethinylestradiol /Levonorgestrel)*			8	10	9	5	18	33
UTROGESTAN® (Progesterone)	Luteal Supplementation in ART	No.2 volume share	7	8	12	11	14	8
DIENOGEST (the same)	Endometriosis	The market continues to expand Our market share is steadily expanding	13	17	16	8	21	12
l'estrogel (Estradiol)	Menopausal disorder	CAGR 10%	2	3	4	2	4	5
Total			**48**	**61**	**69 (32)** 1H Actual	**38**	**90**	**100**

* Drug prices not listed

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I would now like to talk a little about the six main products that I have been explaining in the past.

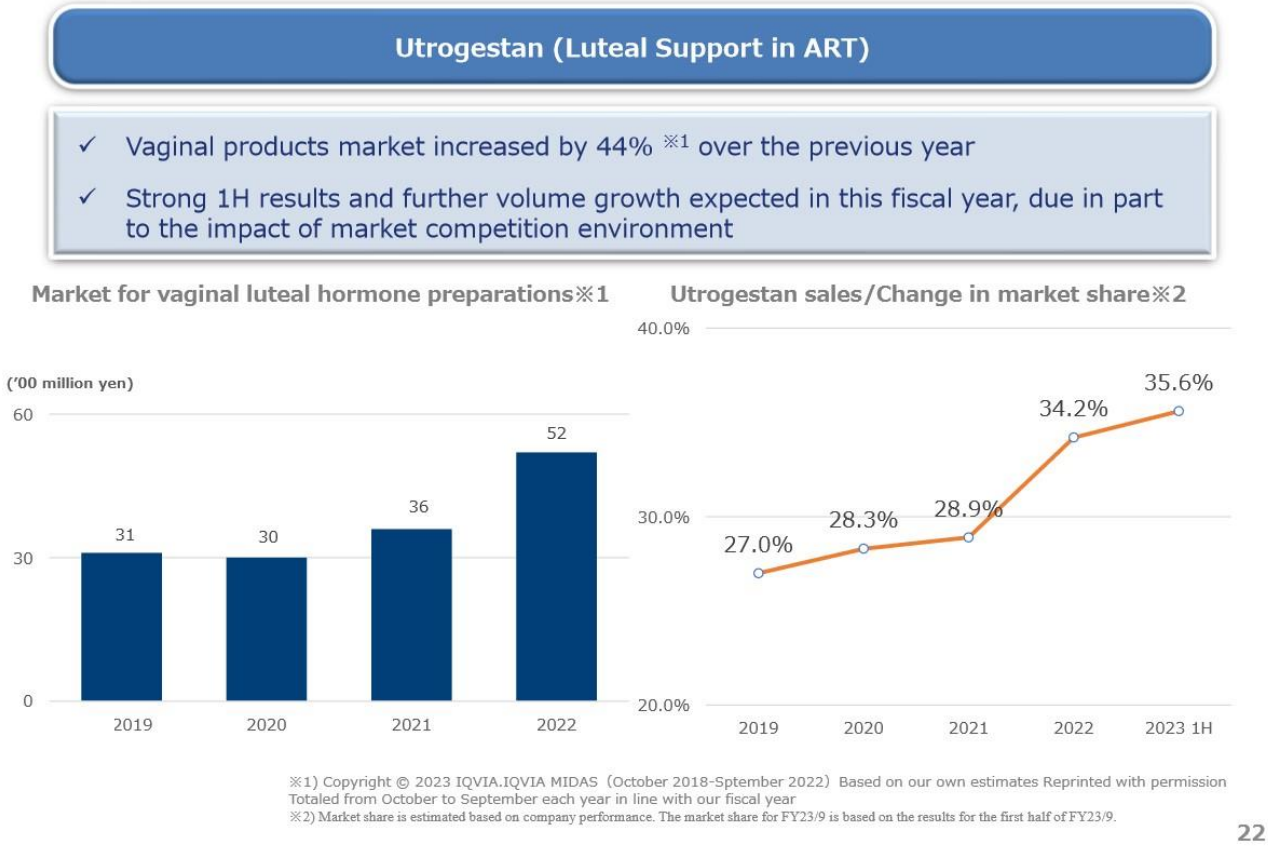
This is a list of the products. The six main products have been growing steadily, from JPY3.2 billion in H1 of the previous year to JPY3.8 billion in H1 of the current year, an increase of JPY0.6 billion.

As for our new progestin drug, UTROGESTAN, the fourth one from the top, which is used in assisted reproductive technologies, sales were JPY1.2 billion in a full-year last year. In H1 of this fiscal year alone, sales expanded to JPY1.1 billion. I think we can say that the market penetration of this product is steadily progressing.

Although each product has its own ups and downs, we expect to achieve our overall plan for the current fiscal year.

From the six products on this slide, today I would like to explain in more detail our position in the field of assisted reproductive technologies, how UTROGESTAN is positioned, as well as oral contraceptives.

①Women's Healthcare (1) Six key products (Utrogestan)



First of all, the left graph on the slide shows the overall market for UTROGESTAN, a product related to assisted reproductive technologies. Our share is shown on the right. The total market for the full year of 2022 was JPY5.2 billion, an increase of about 44% from 2021.

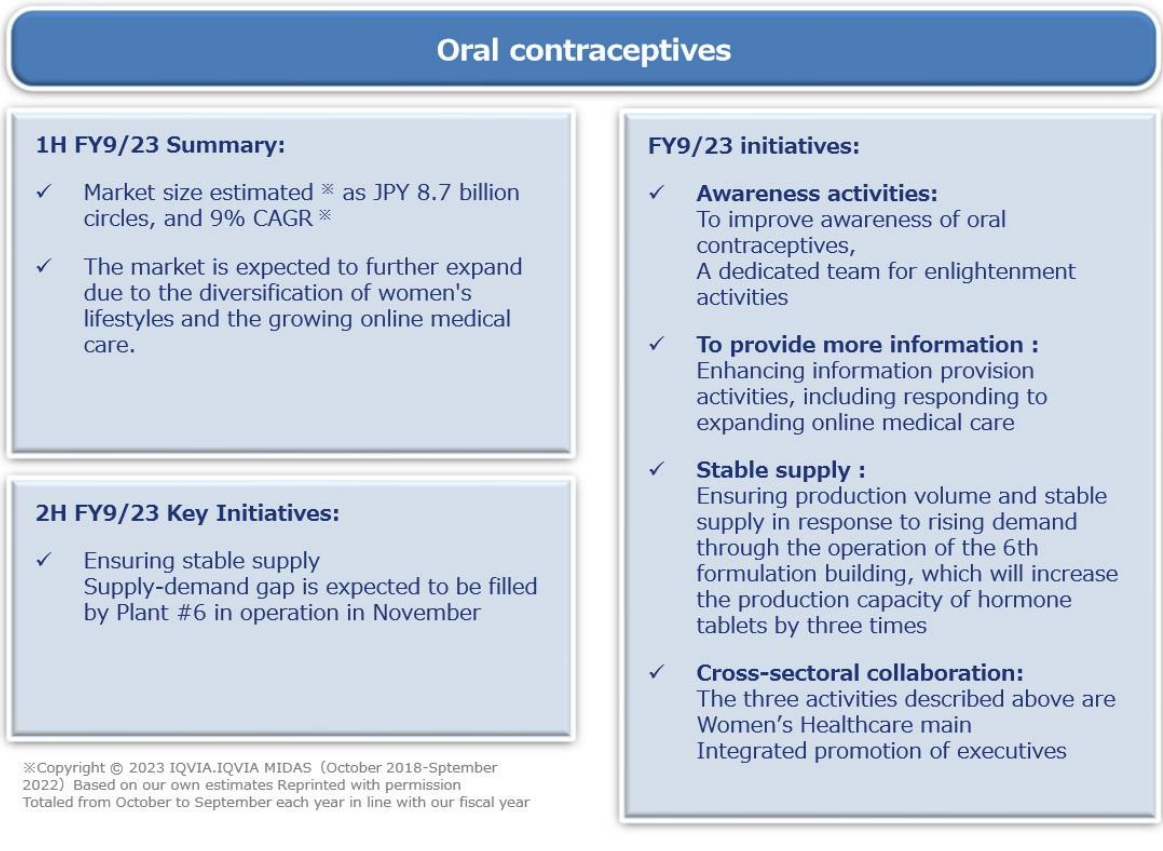
The main factor is the expansion of the market due to the introduction of insurance coverage for infertility treatment.

In this environment, the market share of our products which was 27% in 2019, has expanded from 27% to 36% in H1 of the current fiscal year ending September 2023. We believe that the penetration of our products and the understanding of patients and medical institutions are steadily increasing.

This trend is expected to continue to progress steadily in H2 of the year, and we intend to explain the importance of this product.

This is all about UTROGESTAN.

①Women's Healthcare (1) Six key products (Oral Contraceptives)



Next is about oral contraceptives. The market for oral contraceptives in Japan is currently growing at a fairly high compound in terms of annual growth rate.

The market last year was approximately just under JPY9 billion. Although it says JPY8.7 billion, the market has grown to about JPY9 billion, with an average annual expansion of about 9%.

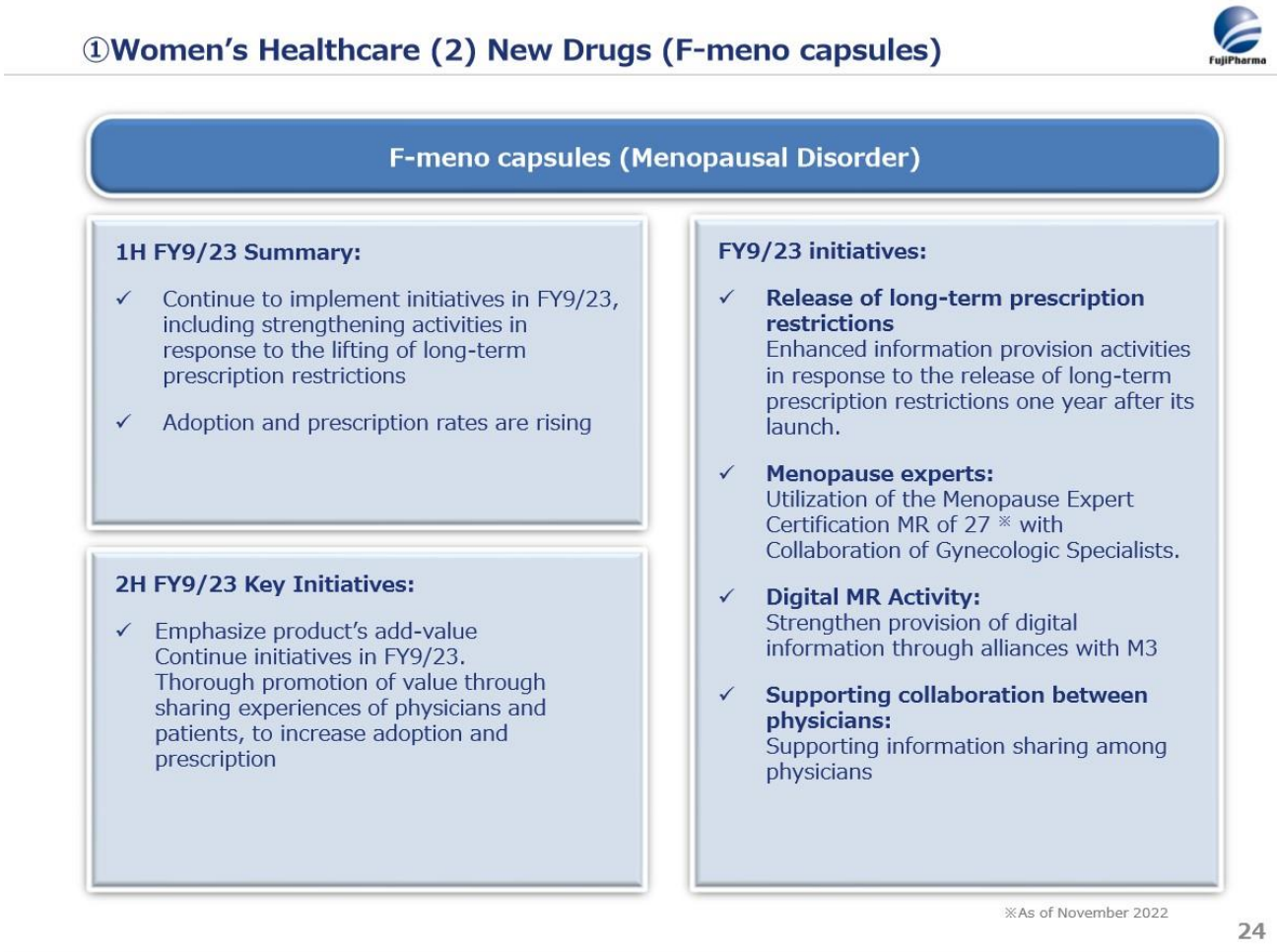
We are currently engaged in the initiatives described in the square on the right. We are also working to raise awareness of birth control pills and to establish a stable supply system to meet the growing demand for these pills. We are mainly working on these two in parallel.

Currently, we are in the process of launching the operation of the sixth formulation building, a dedicated hormone formulation manufacturing facility. We are currently building a system to fill the gap between supply and demand and to ensure the delivery of needed pharmaceuticals to patients and medical institutions.

Although we fell slightly short of our plan for H1 of the fiscal year, we will soon have a system in place to respond to demand. So, we are making steady progress in this area as well.

Comparing H1 of the previous year with H1 of the current year, sales for H1 of the previous year were JPY1.2 billion for both drugs combined. The sales are JPY1.3 billion for H1 of the current year, indicating that the expansion trend is steadily progressing.

This is all about an in-depth explanation of our six main products.



Next, I would like to explain a little about the progestin, F-meno capsules, which were launched the year before last.

This drug is a progestin, the main ingredient is the same as UTROGESTAN, which has already been approved. As the only natural progestin product indicated for hormone replacement therapy during the menopause period, we received approval in September of the year before last and launched the product in December of 2021.

In this context, as noted at the top right, the one-year restriction on long-term prescriptions was lifted in the last December 2022. As a result, clinics and hospitals are now adopting these products in a big way.

Sales for the same period last year were JPY100 million, but for H1 of the current fiscal year, sales are estimated to be just under JPY1 billion. So, although the penetration rate is still insufficient, we are making steady progress in penetrating medical institutions and patients.

I would like to talk about the story behind the development of this drug again. The Japan Society of Obstetrics and Gynecology, JSOG, and the Japan Society for Menopause and Women's Health, JMWH, originally requested us to develop this drug, and the Ministry of Health, Labor and Welfare (MHLW) determined that there was a high medical need for this drug at a review meeting for unapproved drugs.

Although the speed of the product's launch is slightly slower than planned at the time the business plan for the current fiscal year was formulated, there will be no change in peak sales in the future, based on the number of target patients. We will continue to provide information on the value of this product, which is

highly needed in the medical field, in order to promote the penetration of this product. This is the explanation regarding F-meno capsules.

Next, in women's healthcare area, we are working on expanding our portfolio a little more, and I would like to explain these efforts in two slides.

These are the products in the women's healthcare area that have been introduced or taken over by another company. As I mentioned in the previous slide, we would like to enhance our product portfolio in the fields of perinatal and women's oncology, and we launched three new products in the previous fiscal year.

The first is a product called Foliamin, which is folic acid and is used for anemia in pregnant women.

Then there is Propess, which is a drug to promote labor and delivery, and Doxil, which is a drug to treat ovarian cancer in women.

By continuing to build a solid portfolio of such products, we intend to accelerate the shift to specialty pharmaceuticals in the field of women's healthcare area.

①Women's Healthcare (2) New Drugs (perinatal area)

Enhance perinatal area by our first medical supplement

女性を満たすサプリメント
LAFILL®
ラフィル

Overview

Product name :	LAFILL® Folic acid + Kestose
Classification :	Nutritional function foods (zinc)
Release date:	June 2, 2023
Brand site:	https://lafill.jp/

Characteristic

- Physician-Directed Supplements for Women Developed with the Concept of Filling Women
- Essential nutritional support for healthy living during important pregnancies
- Supporting women who have visited the OBGYN to create an environment where they can consult with their doctors on an ongoing basis, contributing to the improvement of women's well-being

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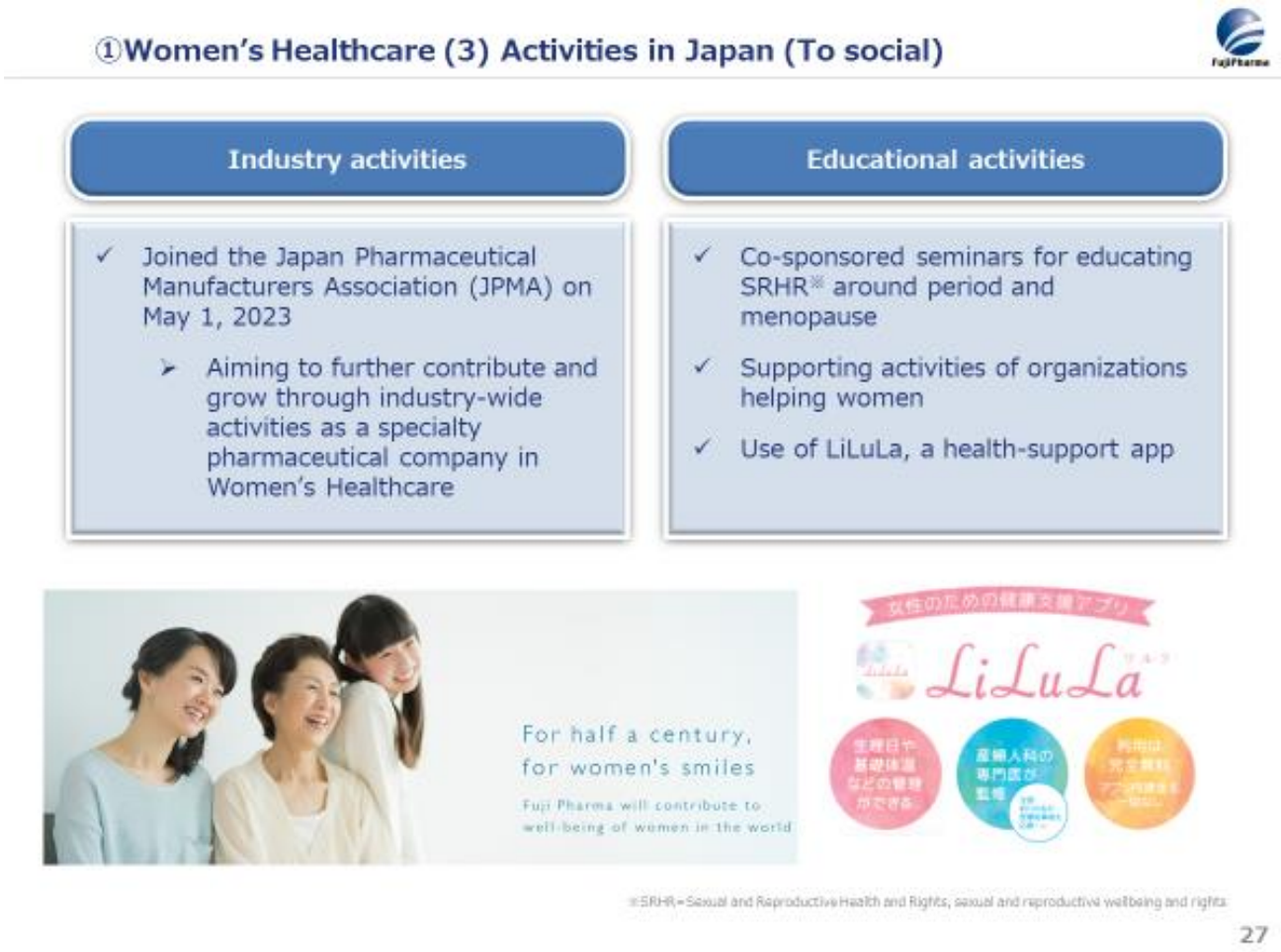
This is all about our initiatives related to pharmaceutical drugs.

In addition to the above, we are planning to launch a new initiative to develop products that are not affected by NHI drug prices, such as supplements for the medical community.

Rather than a multi-purpose supplement that can be used in a variety of fields, we are currently developing a supplement that is focused on a specific purpose and will be sold through the medical route.

The first product is LAFILL, a supplement for pregnant women during the perinatal period. We would like to launch this product under the guidance of the doctor through the medical route as well.



By strengthening our portfolio with these products, we aim to become a specialty pharmaceutical company in the field of women's healthcare.

On the other hand, I would like to tell you something about the next two slides. We are aware that our company's recognition in fieldwomen's healthcare field is not growing well, both domestically and internationally, so we are currently promoting industry activities and educational activities in order to further increase the recognition of our company in the field.

One of the major aspects of this is newer products. In order to deliver new medicines in the area of women's healthcare, the continuous development of new drugs will become even more important for our company. We has launched new drugs, UTROGESTAN, F-meno capsules. And we are currently developing a new drug, FSN-013 which I will explain later, but we must firmly establish the next pipeline.

Therefore, we have decided to withdraw from the Japan Generic Medicines Association at the end of April and join the Japan Pharmaceutical Manufacturers Association (JPMA), of which original manufacturers are members, as of May 1.

While receiving a wide range of information from JPMA, we would like to develop drugs that will be useful to patients and medical institutions by taking advantage of our company's unique characteristics.

As for our overseas activities, our company's name recognition is relatively low in Europe, the US, and Asia because our activities have been focused on the domestic market.

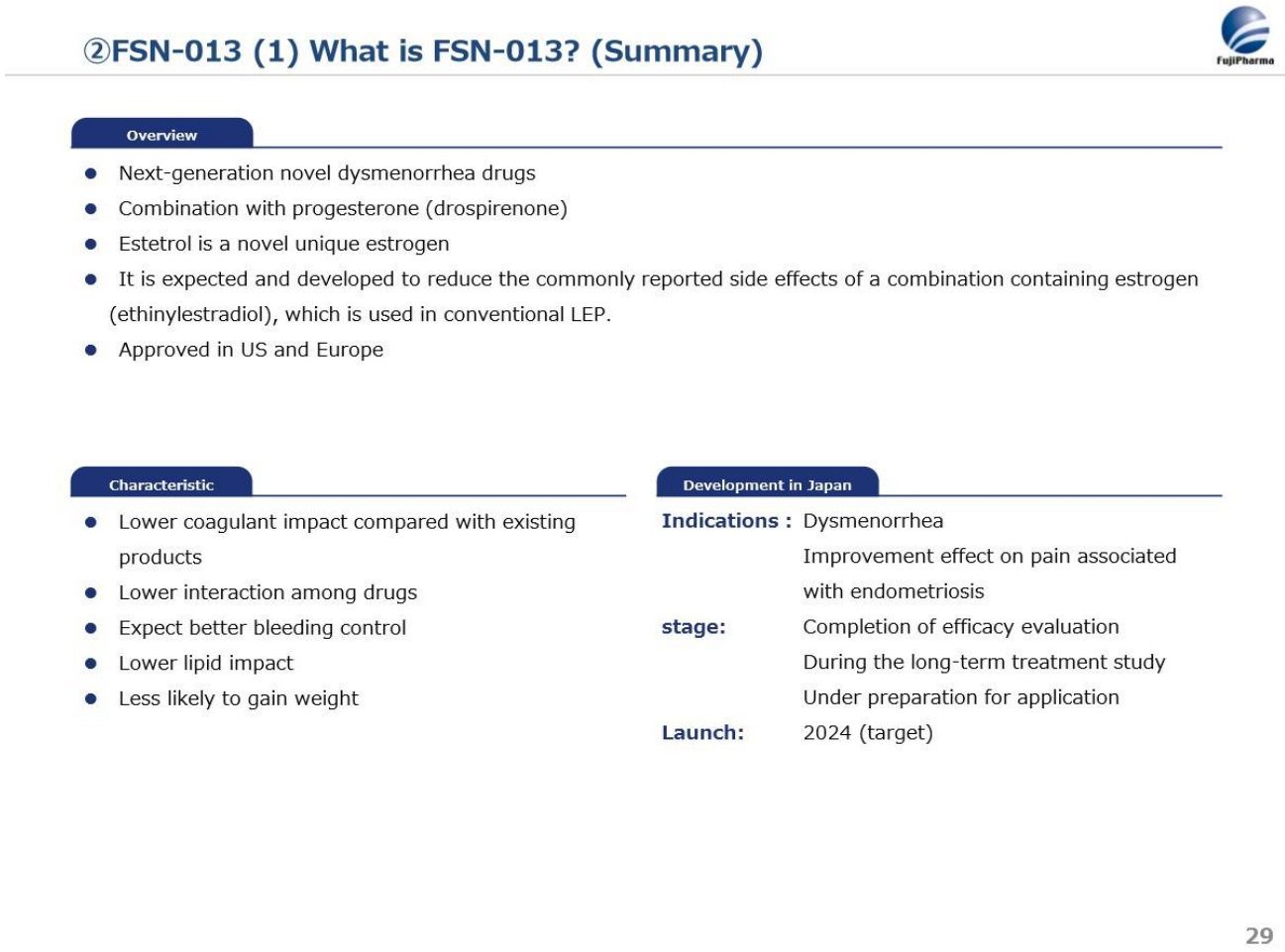
With this in mind, we have begun to actively increase our exposure to world-class events and academic conferences in H1 of this fiscal year.

We are a co-sponsor and participant in the Women's Health Innovation Summit, a global event in the field of women's healthcare, for the first time. We would like to continue this kind of event in order to improve our company's recognition as Fuji Pharmaceuticals is synonymous with women's healthcare.

In Asia, as in the photo in the middle, we had a booth at the Royal Thai College of Obstetrics and Gynecology, an academic conference for doctors, for the first time as a sponsor.

As you can see in the photo on the right, we took the opportunity of this conference to hold a launch event in Bangkok for a new estrogen-based drug called Estetrol, which has been approved as an oral contraceptive in Asia. I will explain this later. About 200 doctors participated in the event. I will touch on this in more detail later.

We will continue to increase our exposure both domestically and internationally, and we would like to increase the recognition of our company that Fuji Pharma Co., Ltd. is known for women's healthcare both domestically and internationally.



Next, I would like to talk about the second major agenda, FSN-013.

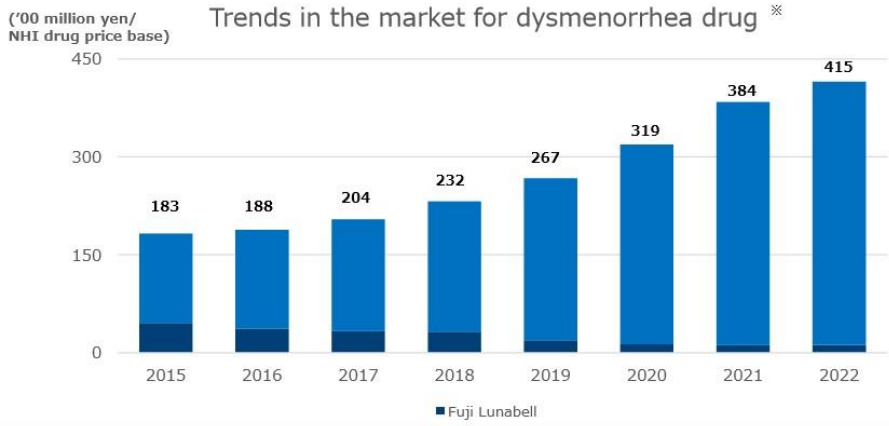
First of all, I would like to talk about FSN-013, which I have mentioned many times in the past, but I would like to explain again what it is.

As you can see on this slide, it is a new estrogen. Although it has not yet been approved in Japan, it is a combination drug of a new estrogen called Estetrol and a progestin called drospirenone.

The features of this area are described in the overview and the features below, but the positioning of this area is to contribute more to the health of patients by taking advantage of these features, which are different from conventional ones.

②FSN-013 (1) What is FSN-013? (Dysmenorrhea Drug Market)

Dysmenorrhea Drug Market and FSN-013



- ✓ Lunabell was launched in 2008 for the treatment of dysmenorrhea, cultivating the market
- ✓ Dysmenorrhea drug market grows into 2.3 times in 2022 compared with 2015 ※
- ✓ Growing interest in improving women's well-being due to more social activities by women and diversification of lifestyles will continue to expand the market.

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I would like to explain the positioning of this product for our company today in the hope that you will deepen your understanding.

As a treatment for dysmenorrhea, we started selling a product called LUNABELL in 2008, and it is sold jointly by our company and Nippon Shinyaku.

The generic version of LUNABELL has already been on the market. Although sales of LUNABELL are currently declining, sales at the peak when the product was launched by our company and Nippon Shinyaku exceeded JPY10 billion on an NHI price basis.

We are currently preparing to apply for FSN-013 in order to further expand the dysmenorrhea market with LUNABELL, which we are continuing to sell at present, and FSN-013 together,

The next slide shows the transition of the dysmenorrhea market. As LUNABELL has penetrated the market, the dysmenorrhea market has been expanding significantly.

I would like to show you some market trends on the next slide.

This is the data from 2015. The total market for dysmenorrhea was JPY18.3 billion in 2015, and the data for 2022 is JPY41.5 billion. It means that the market has expanded 2.3 times over the past 7 years.

This trend is expected to continue due to women entering the workforce and diversifying lifestyles.

Naganawa of the Research and Development Department will explain the status of clinical trials for FSN-013, the successor to LUNABELL. Before passing to Naganawa, I would like to briefly talk about the current status of FSN-013 in Asia.

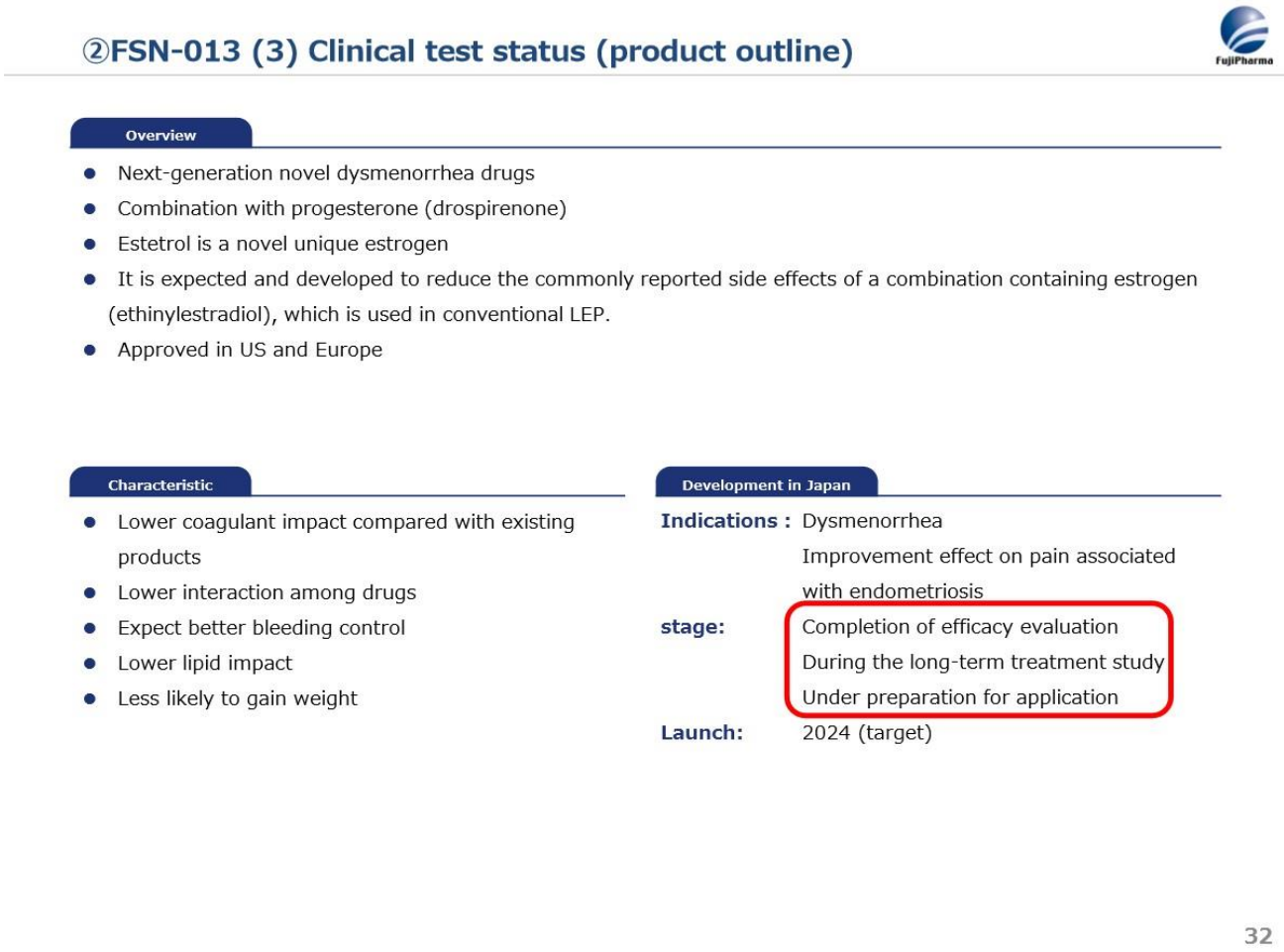
As I mentioned on slide 28, the trademark name for FSN-013 in Asia is Nextstellis, which was approved last September. We held a launch event in Bangkok, Thailand last month.

The photos shown here are from the launching event. Professor Creinin of the University of California in the US attended the event and gave a lecture to about 200 Thai obstetricians and gynecologists who gathered for the event.

Since this ingredient, Estetrol is not yet available in Asia, Thai doctors asked many questions about its efficacy and mechanism of action and showed great interest in it.

This product will be marketed as a contraceptive in Asia. Following its approval and launch in Thailand, we plan to obtain approval in Indonesia, Singapore, and other Asian countries in the future.

Lastly, Naganawa will explain the status of the clinical trial for FSN-013, which is currently indicated for dysmenorrhea in Japan, not a contraceptive.



Naganawa: I am Naganawa from the Research and Development Department. I would like to explain the clinical trial status of FSN-013.

In Japan, this drug is being developed for the indication of improving pain associated with dysmenorrhea and endometriosis.

It is in the development stage, but we have completed the evaluation of efficacy and safety in a domestic phase III study and have verified the superiority of the drug over placebo. Now, we are preparing to submit an application.

②FSN-013 (3) Clinical test progress report (FSN-013-03 Study)

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 （PⅢ）
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 Pharmacokinetics: Plasma concentration of E4 and DRSP

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Next, I will explain about the Phase III clinical trials.

In Japan, two phase III clinical trials have been conducted. First, here is an overview of the study plan for dysmenorrhea patients.

The design is a multicenter, double-blind, and placebo-controlled trial.

The target number of cases is 150 patients, 75 in the FSN-013 group and 75 on placebo.

As you can see here, the dosage and administration for FSN-013 is 24 days of drug administration, followed by 4 days of placebo administration, and 28 days of placebo administration. The entire period is 28 days, which is one cycle.

The administration period was 4 cycles for the comparative study period, followed by up to 13 cycles for the continuous administration period.

The primary evaluation items are the change in the total dysmenorrhea score from the baseline observation period to the 4 comparative study periods, or 16 weeks. In addition, we evaluate the safety of drug administration.

②FSN-013 (3) Clinical test progress report (FSN-013-04 Study)

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 （PⅢ）
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 Pharmacokinetics: Plasma concentration of E4 and DRSP

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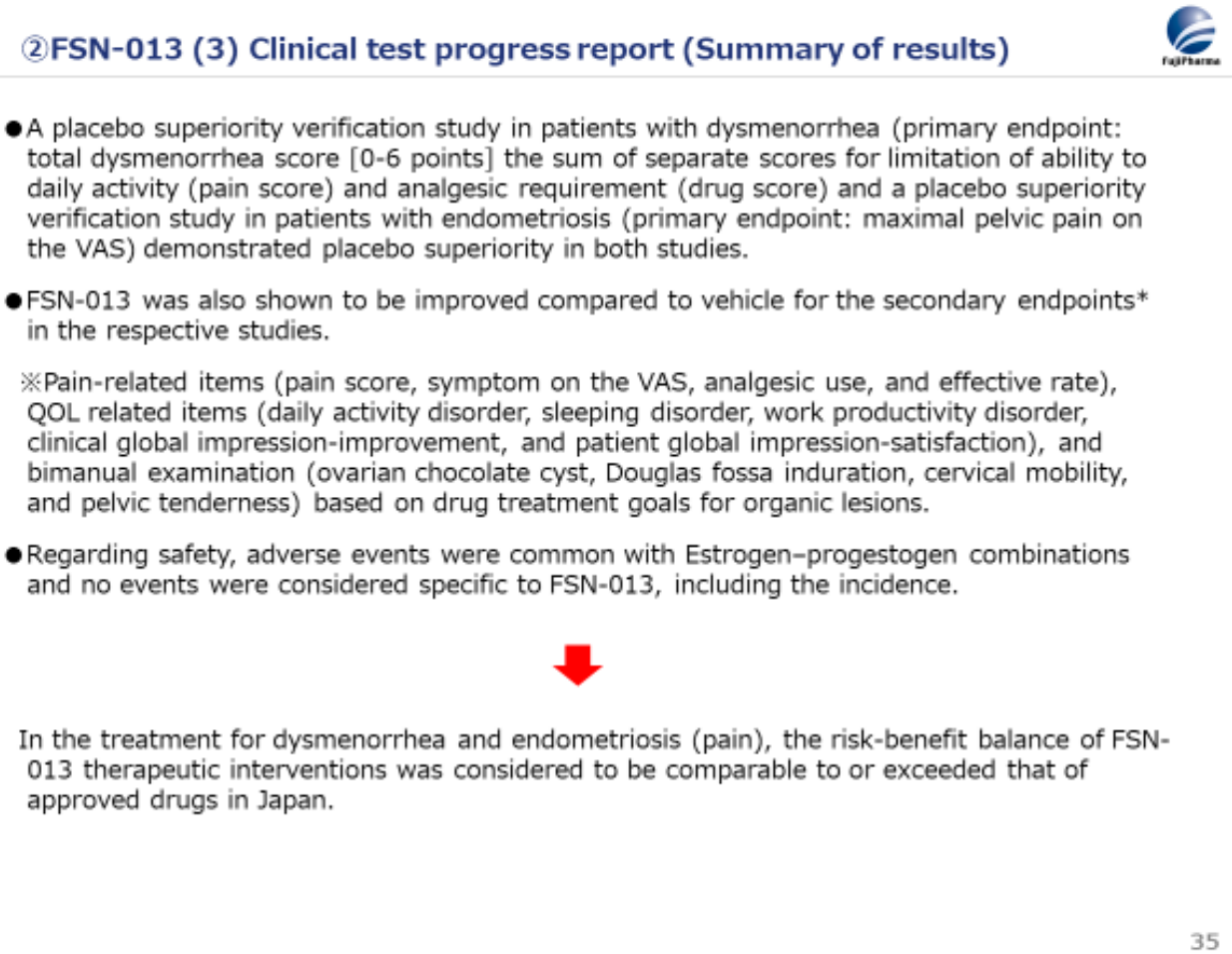
The following is a summary of the study plan for endometriosis.

Like the previous study, this one is also being conducted in the form of 150 cases with 75 cases per group.

Dosage and administration are the same as for dysmenorrhea.

The comparative study period consisted of 6 cycles of 24 weeks, followed by a continuation period of up to 13 cycles.

The primary evaluation item is the change in the most severe pelvic pain from the baseline observation period to the 24-week comparison period, and the amount of change in VAS values. Safety evaluations were also conducted.



This is the test results. Patients with dysmenorrhea and endometriosis showed efficacy with each successive cycle after administration. Also, at the time of evaluation, the superiority of the drug over placebo was verified.

In addition, studies in endometriosis patients have shown improvement in pain-related items, QOL-related assessment items, and twin medical examinations such as ovarian chocolate cysts, Douglas fossa induration, cervical mobility, and pelvic tenderness.

Safety in drug administration. The events commonly observed with EP combination drugs were observed, and there were no events specific to this drug, including incidence.

Based on the above, we believe that the risk-benefit balance of FSN-013's therapeutic intervention in the treatment of dysmenorrhea and pain for endometriosis is comparable to or superior to that of drugs approved in Japan. We are considering presenting these results at next year's conference.

We are currently in the process of preparing an application submission.

That is all from me.

Iwai: Now, I would like to conclude with a little summary from my side.

I have made a long explanation, but we would like to further strengthen our strengths in the area of women's healthcare, and in this way, we would like to become a specialty pharmaceutical company.

As for the forecast for this fiscal year, as shown here, H1 results were 45% of the plan, but the full-year forecast is in line with the plan, with net sales of JPY43.3 billion for the current fiscal year, compared with consolidated net sales of JPY36 billion in the previous year, and consolidated operating profit of JPY4 billion, compared with JPY3.5 billion in the previous year.

We expect an increase in both sales and profit for the full year as per the current plan.

In the field of women's healthcare, the launch of our new drug, F-meno, has been slightly delayed compared to our plan. As I explained earlier, we will continue to maximize product value by steadily penetrating the market.

In the larger scheme of things, the clinical development of FSN-013 is progressing well.

We also filed our first biosimilar application last October as planned. We are steadily expanding our product portfolio for the future, so we intend to steadily move forward with these efforts to make them the pillars of our future.

This is a bit long, but I would like to conclude my explanation.

Thank you very much.

Moderator: President Iwai, Executive Corporate Officer Sato, and Corporate Officer Naganawa, thank you for the explanation.

Question & Answer

Moderator [Q]: I will now move on to the question and answer session. Please feel free to send us your questions via chat. We look forward to receiving your messages.

Yes, thank you for your many questions.

Now, let me start with the first question. So, the first one is this one. The NHI price revision rate is positive this time, but was it factored into the earnings forecast for the fiscal year ending September 2023? If not, please explain why you did not revise your earnings forecast. We have received this question.

Iwai [M]: Yes, thank you. I would like Sato to answer your question.

Sato [A]: Yes, my name is Sato. I would like to answer. The first part of the question was that the NHI price revision is plus now but how it was factored into the earnings forecast, and if it was not factored in, whether the earnings forecast would not be revised.

First, let me explain the first half of the question. In the earnings forecast, the NHI price revision was expected to be negative overall. So, the fact that it was a positive revision was not factored into the forecast.

The second question is whether that will lead to a revision of the earnings forecast. As you pointed out, if we consider it as a single product, the cost of making it remains the same, so if the unit selling price goes up, we will be able to make a profit. However, when the price of a product goes up, there is an impact on market demand. The impact on volume will vary from item to item.

Therefore, it is difficult to make a definite statement as to what will happen in H2 of the fiscal year at this point. The full-year forecast remains unchanged.

If it becomes necessary to revise the earnings forecast in the course of future developments, we will promptly disclose this information.

These are the answers to your questions.

Moderator [Q]: Yes, thank you. Now for the next question. Next, regarding biosimilars, I understand that you have filed an application for one product, but could you tell us about your company's biosimilars situation overall and the progress and challenges you face? Now, please answer this one as well.

Iwai [M]: Thank you very much. I, Naganawa would like to answer.

Naganawa [A]: Yes, thank you for your question. As for biosimilars, as announced in the release, we are currently developing seven products with Alvotech in Iceland.

We applied for one item last October 2022. Basic agreements have been reached and development is underway for the remaining six products.

For biosimilars, we believe that the order in which the products are launched is very important, and we are currently working on the review process for this product so that it can be launched first.

We will continue to work with Alvotech so that we can continue to bring out products in the future. We will work to bring the product to market as scheduled.

As for administrative trends, Iwai would like to answer.

Iwai [A]: The status of Alvotech's efforts is as Naganawa just mentioned, and the MHLW has set a target of increasing the percentage of ingredients that are replaced by more than 80% of the predecessor products to more than 60% by the end of FY2029 on a volume basis. Therefore, I expect that the biosimilars market will expand in the future with the support of the government, although there are still some problems to be solved. I would like to answer the above regarding biosimilars.

Moderator [Q]: Yes, thank you very much. Now for the next question. Next, the NHI price revision this year has made contrast agents the same or more expensive than brand-name products. I would like to know about your future sales strategy. Now, please answer this one.

Iwai [A]: Yes, thank you for your question. You are correct, and there are now quite a few drugs that are priced the same as the original product. We have a very high market share in the hospital market, and we are concerned about the negative impact of losing the price difference with brand-name products in this market.

On the other hand, the Fuji Pharma brand in the contrast agent field has become well known. So, I think there will be an impact that the NHI price is at the same as the original, but I wonder to what extent this will be reflected in the market in the future.

This just started in April, so we will be watching the situation more closely. This is an answer to your question.

Moderator [Q]: Yes, thank you. Now for your next question. Next, please tell us the main reason for OLIC's 140% sales increase over the previous fiscal half. We have received this question.

Iwai [M]: Yes, thank you. Sato will answer this question.

Sato [A]: Yes, my name is Sato. The question is the reason why OLIC's sales went up 40%. OLIC launched a new drug in April as a manufacturing and sales business, but the majority of current sales and profits come from outsourcing.

The increase in the volume of new orders and orders from existing clients has been a major contributor.

For example, we have received requests from major clients to install new equipment and increase production volume because demand has been growing considerably. I wonder if COVID-19-related issues are contributing or not, but demand has been increasing, and we have been able to improve our business performance by responding to this demand.

We are also working on a new contract for the US market in OLIC, which was inspected by the FDA and found out that there were almost no problems. If we can increase the number of such contracts for developed countries in the future, we expect that our business performance will grow even more steadily. These are the answers to your questions.

Moderator [Q]: Yes, thank you. Now for the next question. Next, Astellas received approval in the US for a formulation that treats hot flashes. Is there any possible impact in the future in Japan, such as competition with F-meno? We received this question.

Iwai [M]: Yes, thank you. This is a difficult question, but Naganawa will explain a little about the difference in the mechanism of action.

Naganawa [A]: Yes, first of all, F-meno is a drug used in hormone replacement therapy. When estrogen is used, the endometrium (the lining of the uterus) becomes thickened, and if it is administered alone, there is a risk that it may become cancerous. Taking F-meno will reduce the side effects here.

The indications are different from those of fezolinetant. I understand that fezolinetant is a non-hormonal drug that exerts its effects by acting on the central nervous system. So, there are two options for its use: hormonal treatment and non-hormonal treatment. Since it will treat the same thing, we believe that there may be some negative impact.

However, looking at the current treatment situation in Japan and considering the very small number of people receiving such medical treatment, we believe that the introduction of new therapeutic agents will increase awareness and recognition of the disease.

We would like to keep a close eye on the situation in the US, as we believe that the market for menopausal treatments will expand. FSN-014, our development for a single Estetrol drug has currently stopped and we are expecting that it will work in a positive way to make a move for the project. That is all.

Moderator [Q]: Yes, thank you. Now, as the time gets closer to the end, we will take the next one as a last question. Now, my last question is: how much do you expect FSN-013's sales to be in Thailand this fiscal year? Now, please answer this question.

Iwai [A]: We just had a launching event this term, so it is difficult for me to give you an exact sales forecast right now, however, under the Thai healthcare system, we have to sell our products in hospitals for the first two years. After the two-year period is over and once the safety of the drug is confirmed, it will be available for sale in pharmacies. The big drive for actual sales will come after the pharmacies start selling the product.

Therefore, we would like to work on communicating with doctors in Thailand that the drug is safe and safer than other drugs for the two-year period. We are hoping that this will lead to big sales after the drug is launched in pharmacies.

Incidentally, the contraceptive market for high-end in Thailand is approximately JPY3 billion, so we would like to target such areas to expand the market and capture market share. This is not a direct answer, but this is the answer from me.

Moderator [M]: Yes, thank you very much. We 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 presentation materials.

This concludes the presentation of the financial results for Q2 of the fiscal year ending September 30, 2023, of Fuji Pharma Co., Ltd. Thank you very much for your participation to the end.

[END]

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