

# FY9/2023 2Q Investor Meeting Materials

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May 19, 2023

**Fuji Pharma Co., Ltd.**

TSE Prime

4554



**FujiPharma**

Chapter 1 **Summary of FY9/23 2Q Consolidated Financial Results**

Chapter 2 **Progress of Mid-Term Business Plan  
(Women's Healthcare)**

Chapter 3 **Summary**



Chapter

**1**

# **Summary of FY9/23 2Q Consolidated Financial Results**

- **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

# 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	FY9/23	YoY Change		FY9/23	vs Fcst	FY9/23	vs Fcst
	First half	First half	Amount	Ratio	First half Forecast	Achievement Ratio	Forecast	Progress Ratio
Net Sales	17,726	<b>19,225</b>	1,499	8.5%	<b>20,144</b>	95.4%	<b>43,311</b>	44.4%
Gross Profit	7,675	<b>7,623</b>	▲ 52	-0.7%	-	-	-	-
Gross Margin	43.3%	<b>39.7%</b>	-	-	-	-	-	-
SG&A Expenses	4,963	<b>5,799</b>	836	16.8%	-	-	-	-
SG&A Margin	28.0%	<b>30.2%</b>	-	-	-	-	-	-
Operating Profit	2,712	<b>1,824</b>	▲ 888	-32.7%	<b>2,003</b>	91.1%	<b>4,048</b>	45.1%
Operating Margin	15.3%	<b>9.5%</b>	-	-	<b>9.9%</b>		<b>9.3%</b>	-
Ordinary Profit	2,866	<b>2,456</b>	▲ 410	-14.3%	<b>2,023</b>	121.4%	<b>4,088</b>	60.1%
Ordinary Margin	16.2%	<b>12.8%</b>	-	-	<b>10.0%</b>		<b>9.4%</b>	-
Profit Attributable to Owners of Parent	1,834	<b>1,772</b>	▲ 62	-3.3%	<b>1,476</b>	120.1%	<b>2,974</b>	59.6%
Profit Margin	10.3%	<b>9.2%</b>	-	-	<b>7.3%</b>		<b>6.9%</b>	-
EBITDAR* <sup>1</sup>	4,974	<b>4,418</b>	▲ 556	-11.2%			<b>10,975</b>	40.3%
EBITDA* <sup>2</sup>	3,822	<b>3,050</b>	▲ 772	-20.2%			<b>7,137</b>	42.7%
Capital Expenditure	3,449	<b>1,088</b>	▲ 2,361	-68.5%			<b>5,715</b>	19.0%
Depreciation (Including Leased Equipment)	1,109	<b>1,226</b>	117	10.6%			<b>2,699</b>	45.4%
R&D Expenses	1,152	<b>1,368</b>	216	18.8%			<b>3,838</b>	35.6%
R&D Expenses Ratio	6.5%	<b>7.1%</b>	-	-			<b>8.9%</b>	-

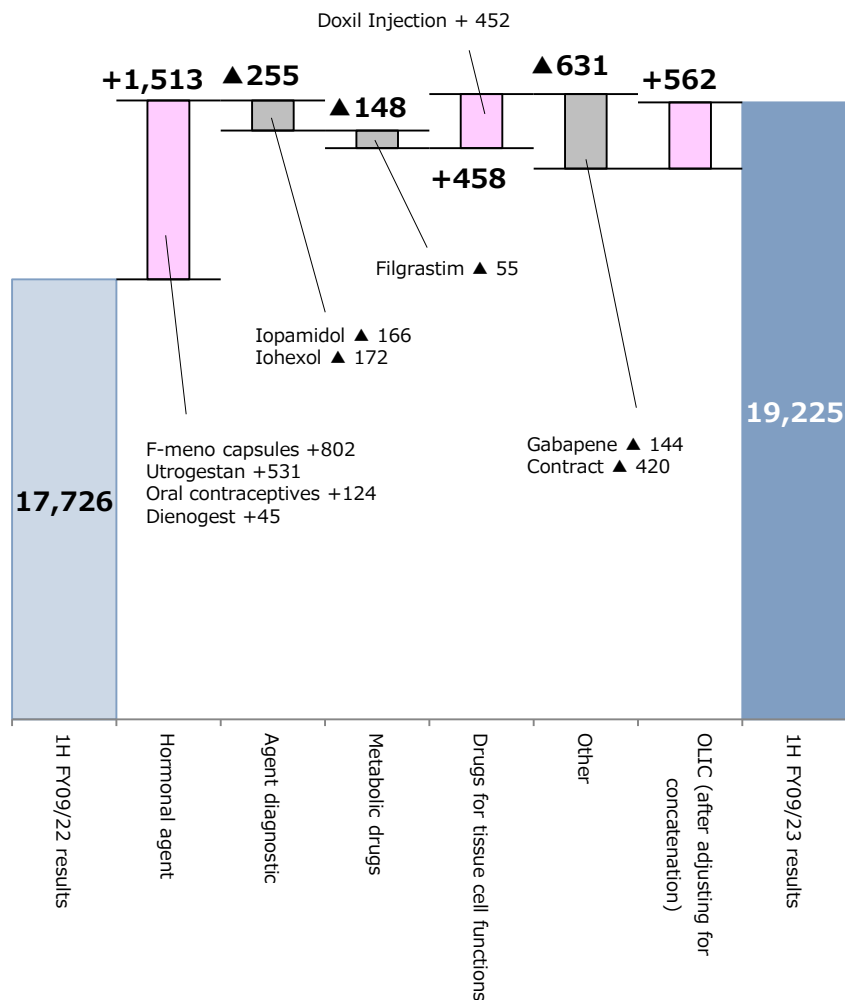
\* 1) EBITDAR : Gross Profit – SG&A Expenses + Depreciation (Including Leased Equipment) + R&D Expenses

\* 2) EBITDA : Gross Profit – SG&A Expenses + Depreciation (Including Leased Equipment)

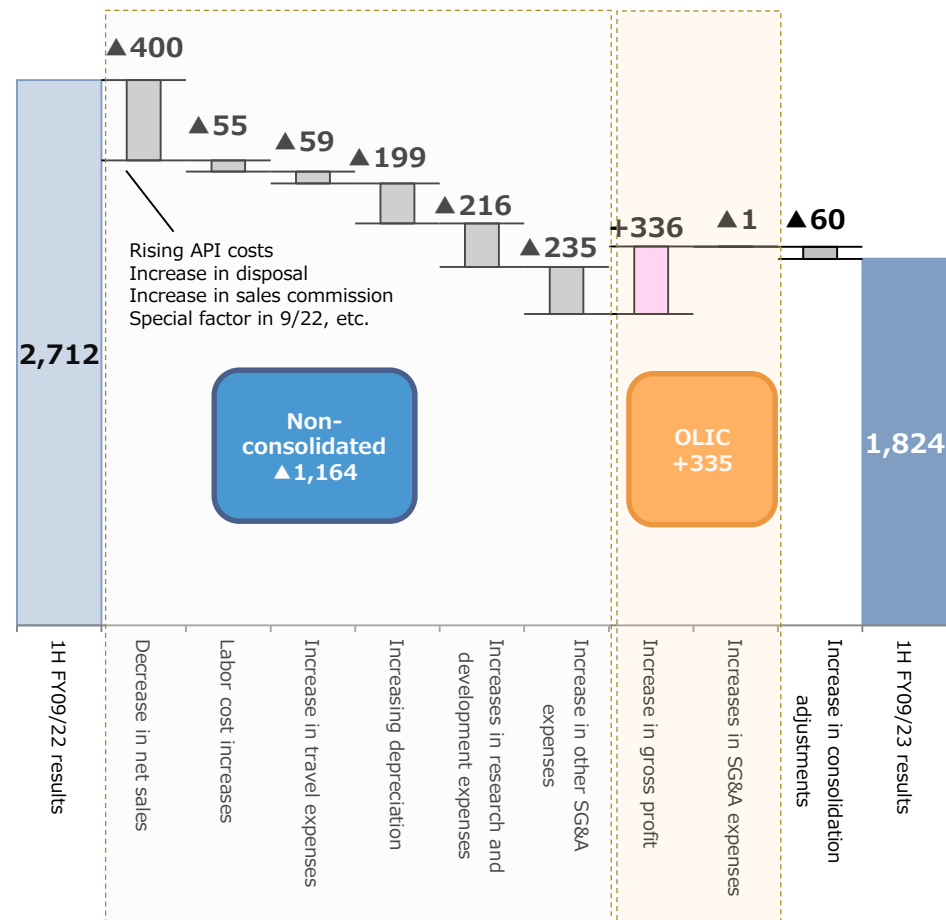
\* 3) There was an error in the full-year forecast figures for Depreciation (Including Leased Equipment), so they have been corrected.

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

Net sales (Unit:¥million)



Operating Profit (Unit:¥million)



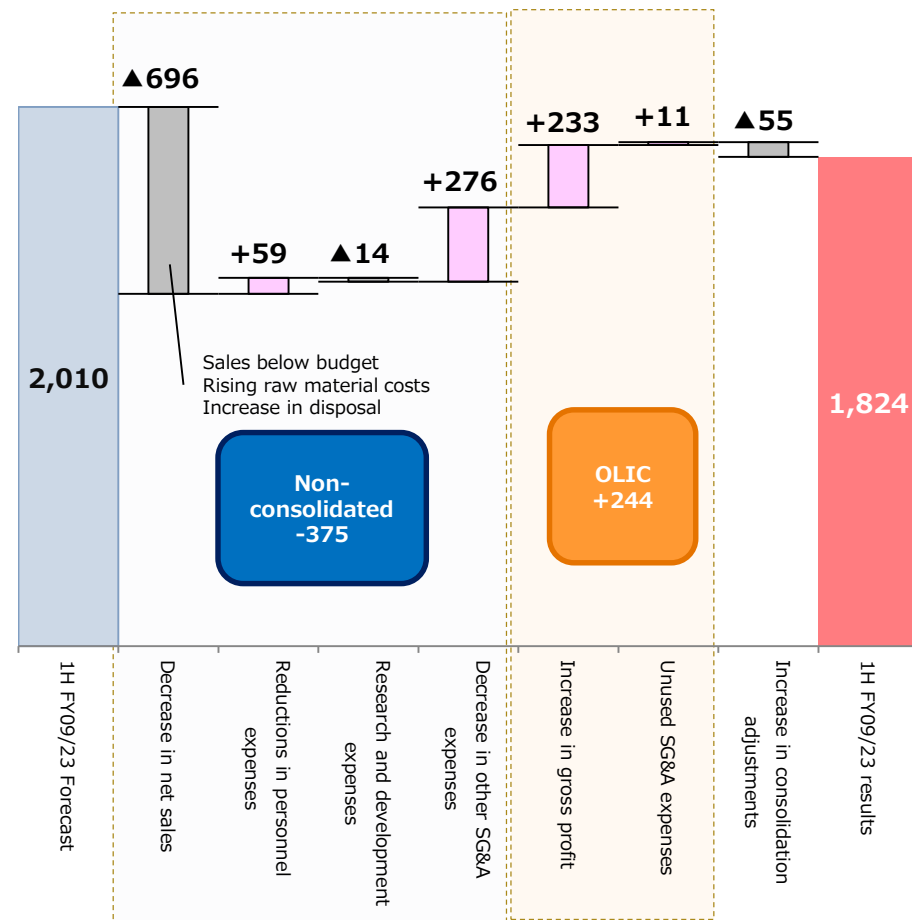
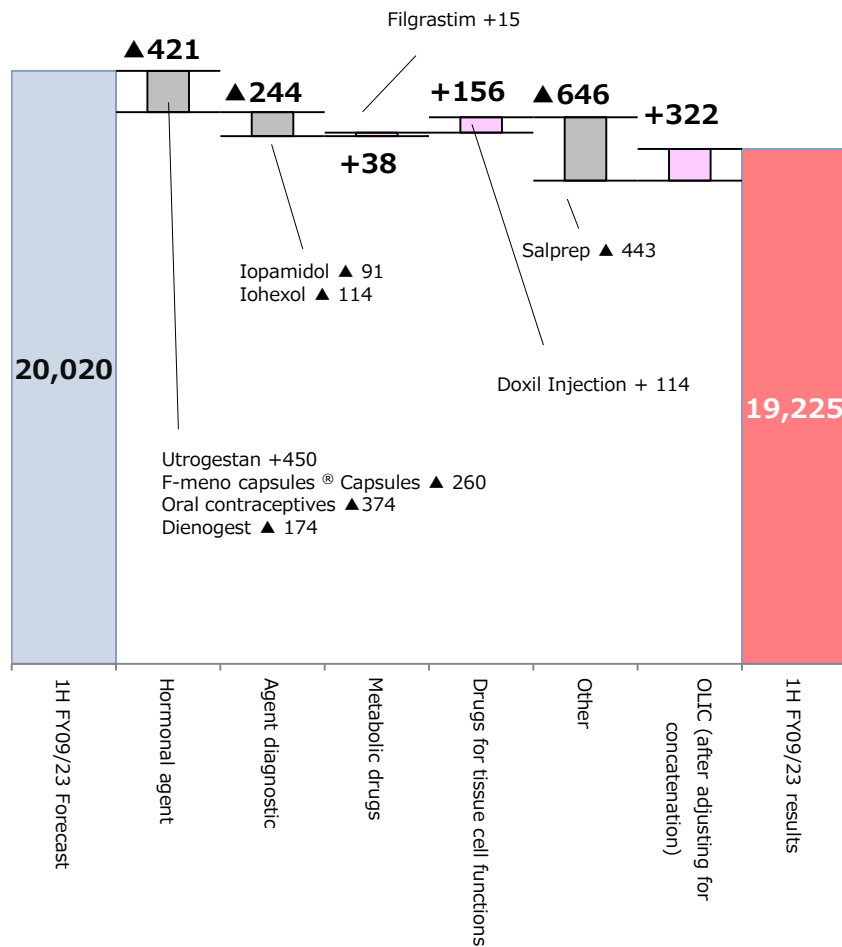
\*1) Change in brand name: Iopamidol (old name: Oypalomine<sup>®</sup> Note), Iohexol (old name: Iopark<sup>®</sup> Note)

\*2) OLIC: Our subsidiary. A CMO company that owns a Thai headquarters and plant

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

Net sales (Unit:¥million)

Operating Profit (Unit:¥million)



\*1) Change in brand name: Iopamidol (old name: Oypalomine<sup>®</sup> Note), Iohexol (old name: Iopark<sup>®</sup> Note)

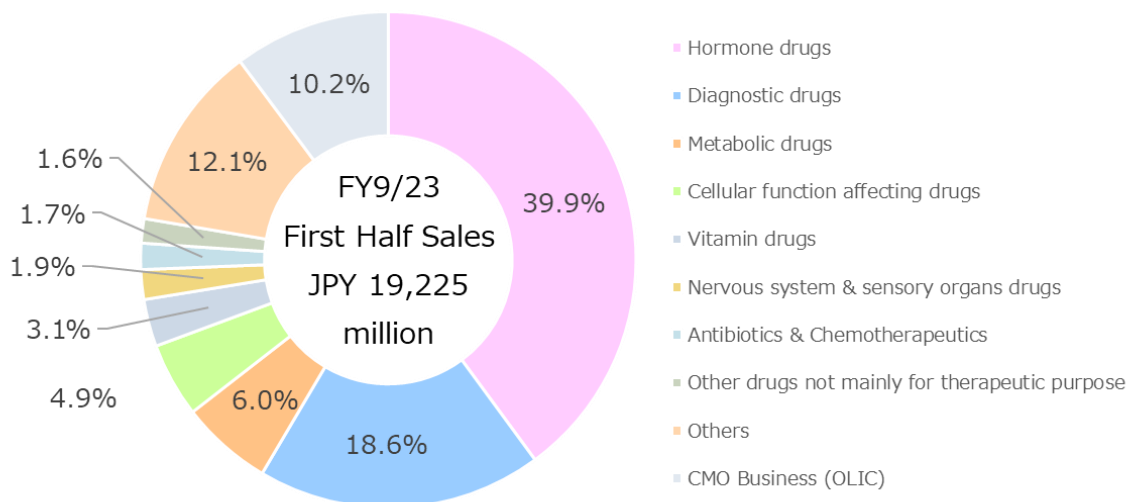
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# Sales by Therapeutic Category

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

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

## Sales Breakdown by Therapeutic Category





# Sales of Top 15 Products

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

# Sales by Medical Field and Drug Form Category

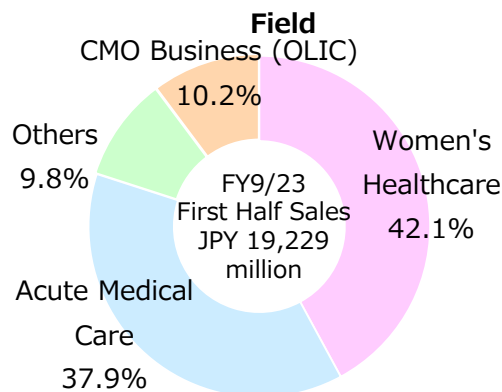
Medical Field Category (¥million)	FY9/19 First half Old accounting standards	FY9/20 First half Old accounting standards	FY9/21 First half Old accounting standards	FY9/22 First half New accounting standards	FY9/23 First half New accounting standards	YoY Change	
						Amount	Ratio
Women's Healthcare	5,154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

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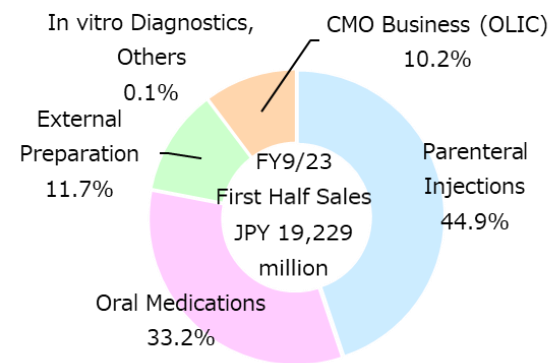
Drug Form Category (¥million)	FY9/19 First half Old accounting standards	FY9/20 First half Old accounting standards	FY9/21 First half Old accounting standards	FY9/22 First half New accounting standards	FY9/23 First half New accounting standards	YoY Change	
						Amount	Ratio
Parenteral Injections	10,998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

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

**Sales Breakdown by Medical Field**



**Sales Breakdown by Drug Form Category**



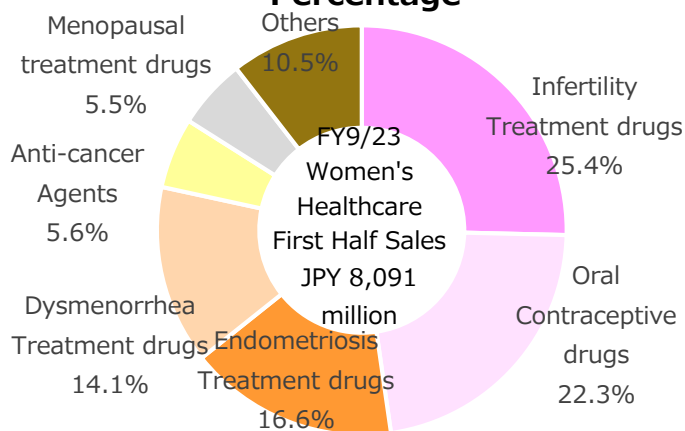
# Sales of Acute Medical Care and Women's Healthcare

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

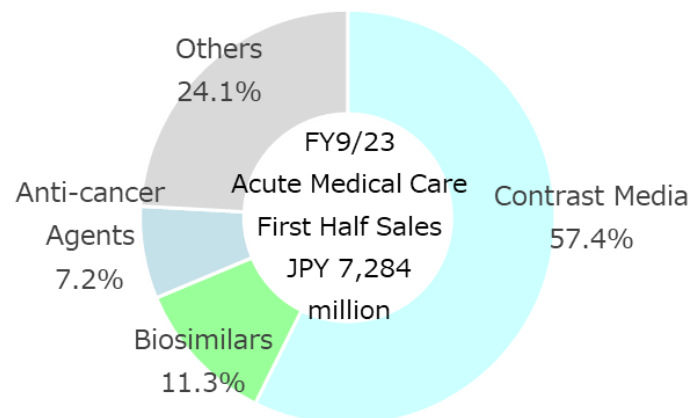
  

Acute Medical Care (¥Million)	FY9/19	FY9/20	FY9/21	FY9/22	FY9/23	YoY Change	
	First half Old accounting standards	First half Old accounting standards	First half Old accounting standards	First half New accounting standards	First half New accounting standards	Amount	Ratio
Contrast Media	6,661	4,796	4,718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

### Women's Healthcare Net Sales Percentage



### Acute Medical Care



# FY9/23 2Q Summary of Consolidated Balance Sheet

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

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

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

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

# 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	<b>43,311</b>	7,345	20.4%	19,225	24,086
Operating Profit	3,349	3,490	<b>4,048</b>	558	16.0%	1,824	2,224
Operating Margin	10.3%	9.7%	<b>9.3%</b>	-	-	9.5%	9.2%
Ordinary Profit	3,250	3,540	<b>4,088</b>	548	15.5%	2,456	1,632
Ordinary Margin	10.0%	9.8%	<b>9.4%</b>	-	-	12.8%	6.8%
Profit Attributable to Owners of Parent	2,432	2,562	<b>2,974</b>	412	16.1%	1,772	1,202
Profit Margin	7.4%	7.1%	<b>6.9%</b>	-	-	9.2%	5.0%
ROIC * 1	8.2%	6.7%	<b>7.4%</b>				
WACC			<b>5.0%</b>				
EBITDAR * 2	7,688	8,059	<b>10,975</b>	2,916	36.2%	4,418	6,557
EBITDA * 3	5,242	5,250	<b>7,137</b>	1,887	35.9%	3,050	4,087
Capital Expenditure	3,392	7,172	<b>5,715</b>	▲ 1,457	-20.3%	1,088	4,627
Depreciation (Includind Leased Equipment)	1,893	1,760	<b>3,089</b>	1,329	75.5%	1,226	1,863
R&D Expenses	2,446	2,809	<b>3,838</b>	1,029	36.6%	1,368	2,470
R&D Expenses Ratio	7.5%	7.8%	<b>8.9%</b>	-	-	7.1%	10.3%

\* 1) ROIC : Operating Profit / (Equity + Net debt) FY09/23 is Forecast

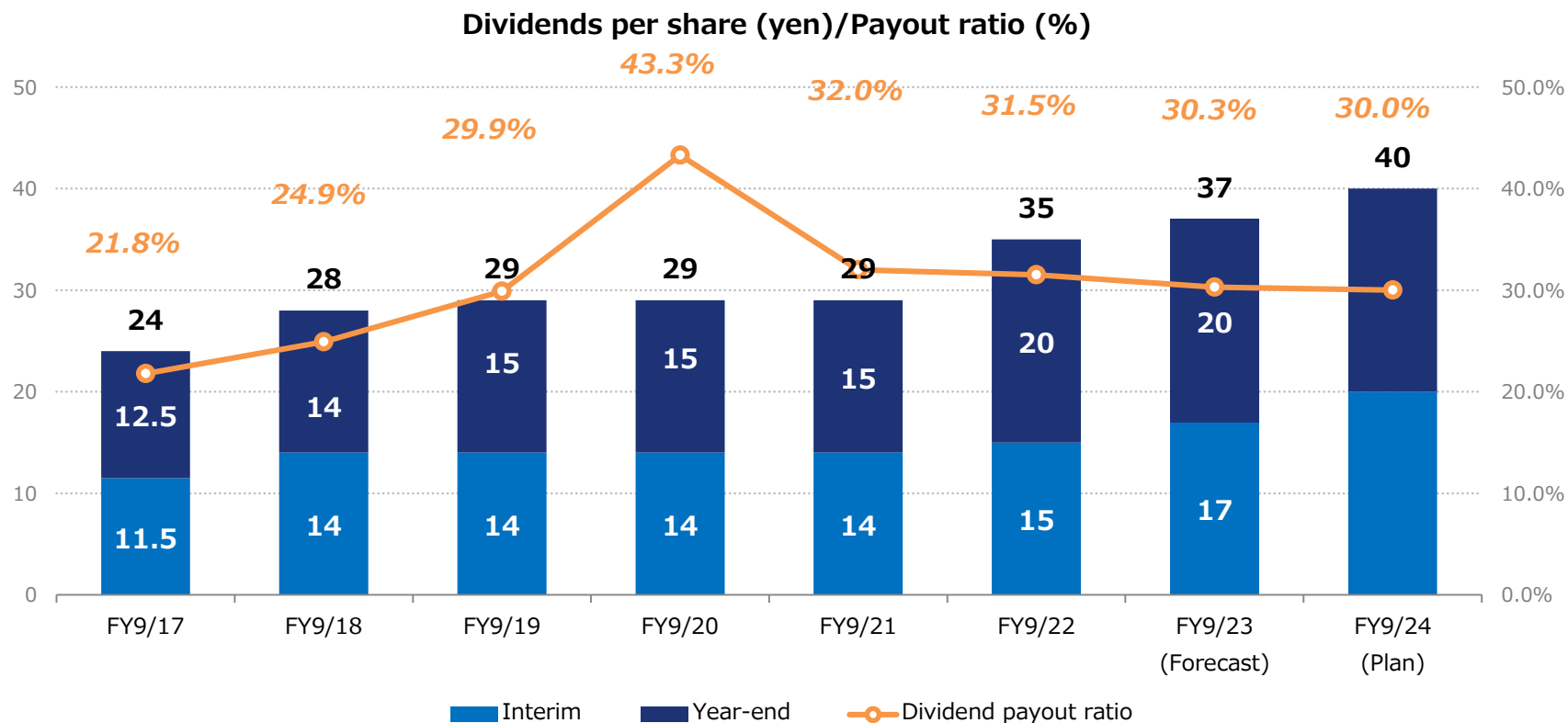
\* 2) EBITDAR : Gross Profit – SG&A Expenses + Depretiation (Including Leased Equipment) + R&D Expenses

\* 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

# 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

Chapter

2



## Mid-Term Business Plan (Women's Healthcare)



Theme

# Fujiらしくをあたらしく

*"Evolving Fuji"*

Target in 9/2029

Goal

Business Plan based on Vision for 2030

Positioning

Roadmap to achieve Vision for 2030

Sales

JPY **100** bil+

Growth Scenario

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

Today's subject

Operating Margin

**20%+**

To Achieve

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

## To " Specialty Pharma of Women's Healthcare "

### ① Women's Healthcare

(1) Six key products

(2) Expansion of new drugs and other areas

(3) Activities in Japan and Overseas

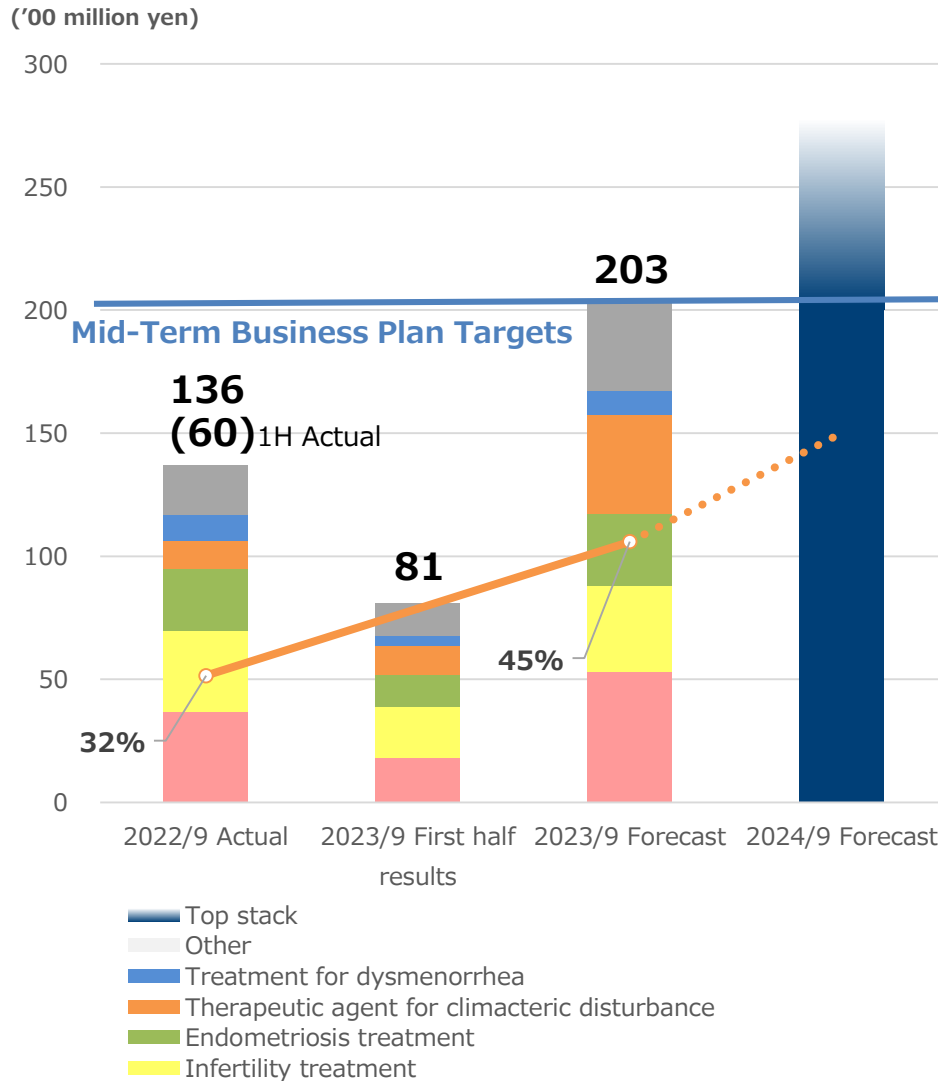
### ② FSN-013

(1) What is FSN-013?

(2) ASEAN

(3) Clinical test progress report

# To " Specialty Pharma of Women's Healthcare "



## Activities in Women's Healthcare

### ① Overall

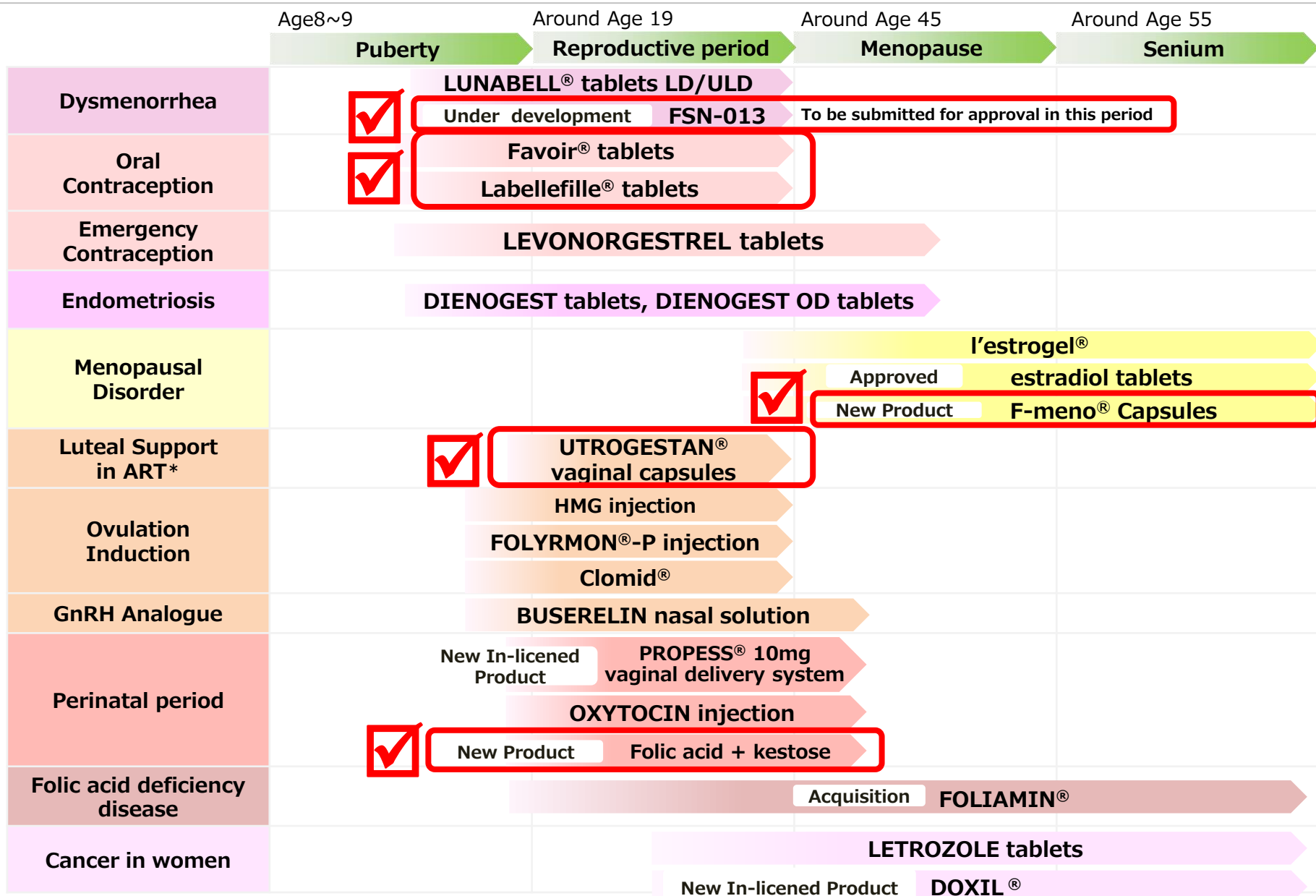
- ✓ Strengthen and expand product portfolio
- ✓ Pursuing inorganic growth opportunities such as product acquisition
- ✓ Expand playing field
- ✓ Industry and educational activities
- ✓ Overseas expansion

### ② FSN-013

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

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

# ① Women's healthcare : Product Portfolio



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

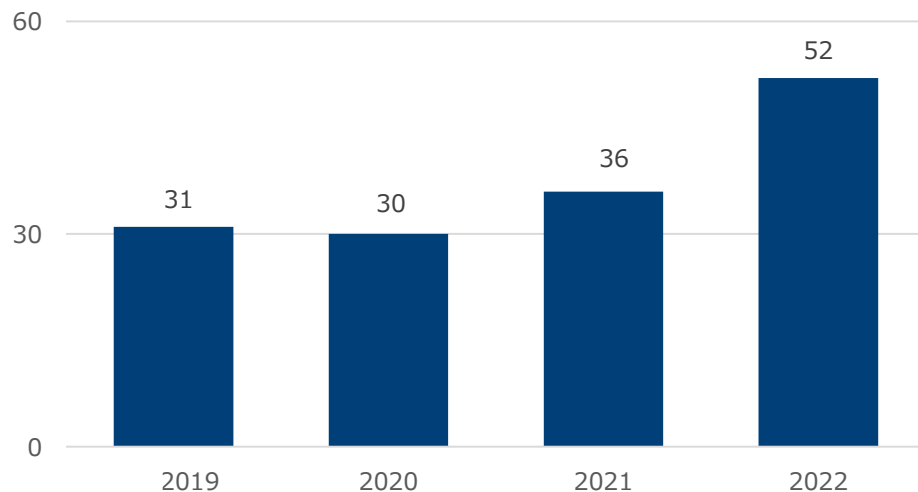
\* Drug prices not listed

## Utrogestan (Luteal Support in ART)

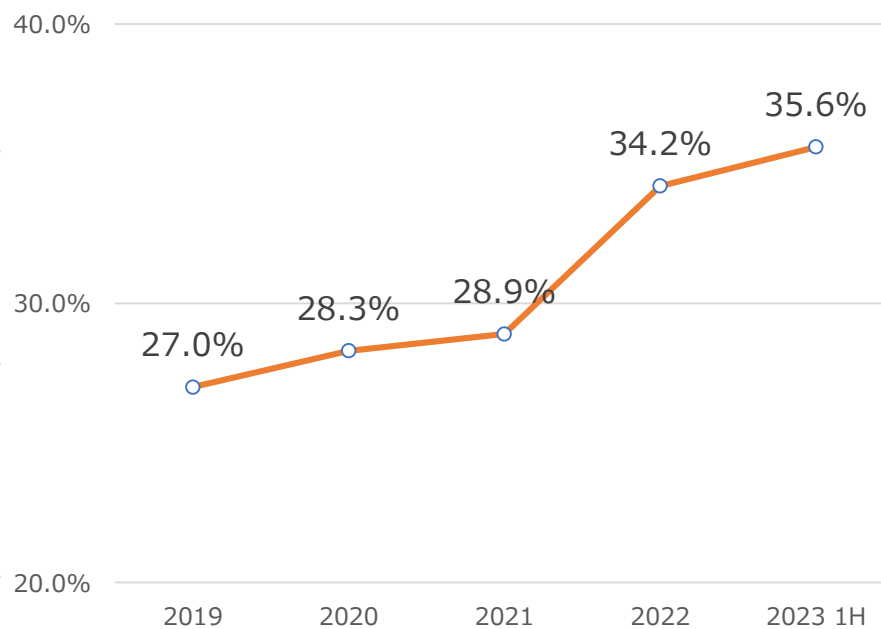
- ✓ Vaginal products market increased by 44% ※1 over the previous year
- ✓ Strong 1H results and further volume growth expected in this fiscal year, due in part to the impact of market competition environment

Market for vaginal luteal hormone preparations※1

('00 million yen)



Utrogestan sales/Change in market share※2



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※2) Market share is estimated based on company performance. The market share for FY23/9 is based on the results for the first half of FY23/9.

## Oral contraceptives

### 1H FY9/23 Summary:

- ✓ Market size estimated ※ as JPY 8.7 billion circles, and 9% CAGR ※
- ✓ The market is expected to further expand due to the diversification of women's lifestyles and the growing online medical care.

### 2H FY9/23 Key Initiatives:

- ✓ Ensuring stable supply  
Supply-demand gap is expected to be filled by Plant #6 in operation in November

### FY9/23 initiatives:

- ✓ **Awareness activities:**  
To improve awareness of oral contraceptives,  
A dedicated team for enlightenment activities
- ✓ **To provide more information :**  
Enhancing information provision activities, including responding to expanding online medical care
- ✓ **Stable supply :**  
Ensuring production volume and stable supply in response to rising demand through the operation of the 6th formulation building, which will increase the production capacity of hormone tablets by three times
- ✓ **Cross-sectoral collaboration:**  
The three activities described above are Women's Healthcare main  
Integrated promotion of executives

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## F-meno capsules (Menopausal Disorder)

### 1H FY9/23 Summary:

- ✓ Continue to implement initiatives in FY9/23, including strengthening activities in response to the lifting of long-term prescription restrictions
- ✓ Adoption and prescription rates are rising

### 2H FY9/23 Key Initiatives:

- ✓ Emphasize product's add-value  
Continue initiatives in FY9/23.  
Thorough promotion of value through sharing experiences of physicians and patients, to increase adoption and prescription

### FY9/23 initiatives:

- ✓ **Release of long-term prescription restrictions**  
Enhanced information provision activities in response to the release of long-term prescription restrictions one year after its launch.
- ✓ **Menopause experts:**  
Utilization of the Menopause Expert Certification MR of 27 ※ with Collaboration of Gynecologic Specialists.
- ✓ **Digital MR Activity:**  
Strengthen provision of digital information through alliances with M3
- ✓ **Supporting collaboration between physicians:**  
Supporting information sharing among physicians



## Initiatives during the Current Medium-term Business Plan

- ✓ **Foliamin:** product acquisition from Nippon Pharmaceutical in October 2022
- ✓ **Proupes:** Sales alliance with Ferring Pharma since December 2021
- ✓ **Doxil Injection:** Sale was transferred from Mochida Pharmaceutical Co., Ltd. in December 2022 (Manufacturer: Baxter)

**FOLIAMIN®**  
(Perinatal period)



**PROPESS®**  
(Perinatal period)



**DOXIL®**  
(Cancer in women)



**Continue to pursue inorganic growth opportunities aggressively such as product acquisition**

## ① Women's Healthcare (2) New drugs (Perinatal area)

Enhance perinatal area by our first medical supplement



### 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

# ① Women's Healthcare (3) Activities in Japan (To social)

## Industry activities

- ✓ Joined the Japan Pharmaceutical Manufacturers Association (JPMA) on May 1, 2023
  - Aiming to further contribute and grow through industry-wide activities as a specialty pharmaceutical company in Women's Healthcare

## Educational activities

- ✓ Co-sponsored seminars for educating SRHR\* around period and menopause
- ✓ Supporting activities of organizations helping women
- ✓ Use of LiLuLa, a health-support app



\*SRHR=Sexual and Reproductive Health and Rights, sexual and reproductive wellbeing and rights

# ① Women's Healthcare (3) Activities Overseas (Development overseas)

## Strengthening overseas activities in Women's Healthcare

Enhancing global recognition and searching for contributing opportunities by sponsoring Women's Health Innovation Summit (Asia/Europe), a global event in Women's Healthcare

## Improving Presence at Overseas Societies

Participate in RCOG\*, the Thai OBGYN organization, as a manufacturer and distributor, and advocate for value provision through FSN-013

\*Royal Thai College of Obstetricians and Gynaecologists



ราชวิทยาลัยสูตินรีแพทย์แห่งประเทศไทย

The Royal Thai College of Obstetricians and Gynaecologists

WOMEN'S HEALTH  
INNOVATION SUMMIT ASIA

WOMEN'S HEALTH  
INNOVATION SUMMIT EUROPE



## ② FSN-013 (1) What is FSN-013? (Summary)

### Overview

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

### Characteristic

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

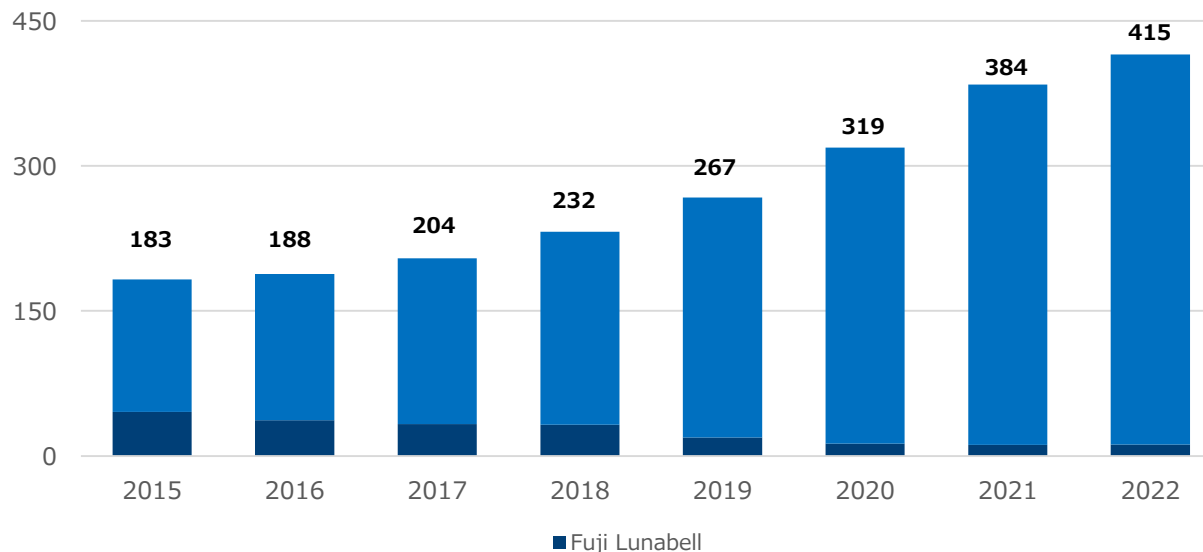
### Development in Japan

- Indications :** Dysmenorrhea  
Improvement effect on pain associated with endometriosis
- stage:** Completion of efficacy evaluation  
During the long-term treatment study  
Under preparation for application
- Launch:** 2024 (target)

### Dysmenorrhea Drug Market and FSN-013

('00 million of yen/  
NHI drug price base)

Trends in the market for dysmenorrhea drug



- ✓ 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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### ASEAN development of FSN-013 (Nextstellis™)

#### Activities in Thailand

- ✓ Launched in April 2023
- ✓ Premium oral contraceptive market in Thailand is approximately ※ \$20 million
- ✓ Enhancing Presence through Launch Events and Seminars

#### Development in other regions

- ✓ In ASEAN major countries (Indonesia, Philippines, Singapore, Malaysia and Vietnam), OLIC is in discussion with sub-licensing destinations

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### Overview

- Next-generation novel dysmenorrhea drugs
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- 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.
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- Indications :** Dysmenorrhea  
Improvement effect on pain associated with endometriosis
- stage:** Completion of efficacy evaluation  
During the long-term treatment study  
Under preparation for application
- Launch:** 2024 (target)



## 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	<p>① The test drug (E4 15 mg/DRSP 3 mg combination tablets) will be administered for 24 days, followed immediately by a placebo tablet for 4 days. A total of 28 days is set as 1 cycle, and a total of 13 cycles of 4 cycles (comparative test phase) and 9 cycles (continuous treatment phase) are administered.</p> <p>② The administration of placebo tablets for 28 days is set as one cycle. Then, this administration is performed for 4 cycles (comparative test phase). Subsequently, the test drug will be administered for 24 days, followed immediately by a total of 28 days of placebo tablets for 4 days are taken as one cycle. Then, this administration is performed for 9 cycles(continuation phase). A total of 13 cycles of administration.</p>
Evaluation items	<p>Primary endpoint : The amount of change in the total score for dysmenorrhea from the baseline run-in period to the controlled study period (4 cycles, 16 weeks)</p> <p>Secondary endpoint : Evaluation scale of pain for dysmenorrhea (VAS) Change from baseline observation phase, etc.</p> <p>Safety endpoint : Incidence of adverse events and adverse drug reactions</p> <p>Pharmacokinetics: Plasma concentration of E4 and DRSP</p>

## ② FSN-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	<p>① The test drug (E4 15 mg/DRSP 3 mg Combination Tablets) will be administered for 24 days, followed immediately by a placebo-tablet for 4 days. A total of 28 days is set as 1 cycle, and a total of 13 cycles of 6 cycles (comparative test phase) and 7 cycles (continuous treatment phase) are administered.</p> <p>② The administration of placebo tablets for 28 days is set as one cycle. Then, this administration is performed for 6 cycles (comparative test phase). Subsequently, the test drug will be administered for 24 days, followed immediately by a total of 28 days of placebo tablets for 4 days are taken as one cycle. Then, this administration is performed for 7 cycles(continuation phase). A total of 13 cycles of administration.</p>
Evaluation items	<p>Primary endpoint: VAS change in most severe pelvic pain (lower abdominal and lower back pain) from the baseline observation period to the comparative study period (week 24).</p> <p>Secondary endpoints: Pelvic pain (lower abdominal and lower back pain) during menstrual or withdrawal bleeding, etc.</p> <p>Safety endpoints: Incidence of adverse events and adverse drug reactions</p> <p>Pharmacokinetics: Plasma concentration of E4 and DRSP</p>

## ②FSN-013 (3) Clinical test progress report (Summary of results)

- A placebo superiority verification study in patients with dysmenorrhea (primary endpoint: total dysmenorrhea score [0-6 points] the sum of separate scores for limitation of ability to daily activity (pain score) and analgesic requirement (drug score) and a placebo superiority verification study in patients with endometriosis (primary endpoint: maximal pelvic pain on the VAS) demonstrated placebo superiority in both studies.
- FSN-013 was also shown to be improved compared to vehicle for the secondary endpoints\* in the respective studies.
  - ※ Pain-related items (pain score, symptom on the VAS, analgesic use, and effective rate), QOL related items (daily activity disorder, sleeping disorder, work productivity disorder, clinical global impression-improvement, and patient global impression-satisfaction), and bimanual examination (ovarian chocolate cyst, Douglas fossa induration, cervical mobility, and pelvic tenderness) based on drug treatment goals for organic lesions.
- Regarding safety, adverse events were common with Estrogen-progestogen combinations and no events were considered specific to FSN-013, including the incidence.



In the treatment for dysmenorrhea and endometriosis (pain), the risk-benefit balance of FSN-013 therapeutic interventions was considered to be comparable to or exceeded that of approved drugs in Japan.



Chapter

3

**Summary**

## FY2023/9 Forecast

- ✓ Significant increase in sales and earnings expected in FY2023/9, compared with the previous fiscal year
- ✓ Sales increased YoY in 1H (progress rate: 45%)
- ✓ Strengthen marketing activities and control expenses in 2H to achieve full-year forecasts
- ✓ Full-year sales and profit forecasts remain unchanged

## Mid-Term Business Plan ~Women's Healthcare~

- ✓ Increase in sales of existing products
- ✓ Portfolio expansion by new drugs and supplements
- ✓ Strengthen presence in Women's Healthcare area by JPMA membership, raising awareness of diseases, and overseas activities
- ✓ Steady progress in FSN-013 development/Launch in Thailand

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# Appendix

## Internal awareness

- ✓ **Holding internal awareness seminars**  
Invited obstetrician-gynecologist as lecturer  
Held seminars for employees on diseases peculiar to women such as menstruation, PMS, and menopause.



## Promotion of women's empowerment

- ✓ **Number of Female BOD members and Management Ratio**  
Female BOD members : 2 (25%)  
Percentage of female managers : 18.0%<sup>※as of 3/2023</sup>
- ✓ **Female recruitment rate**  
New Graduate : 75.0%<sup>※4/2023 entry</sup>  
Mid-Career : 36.8%<sup>※10/22 - 3/23</sup>
- ✓ **Child-care leave rate** <sup>※FY9/22</sup>  
Female :100%  
Male :31.8%
- ✓ **Fuji well-being Project**  
Male as well as women participate.  
We aim to achieve a state that the happiest company in the world and social contributions are integrated.

## Internal and external trends surrounding biosimilars

### Fuji's trend

- ✓ Seven products in total agreed with Alvotech (domestic market-size of innovator drugs: total over 413 billion yen)
- ✓ Aim to launch the first product by the end of this year

### Current trends

- ✓ MHLW aims "to make the percentage of ingredients with a replacement rate of 80% or more from original products to 60% or more" by volume by the end of fiscal year 2029.
- ✓ At the moment 16% (3 components/18 components)

### Challenges for BS Penetration

- ✓ Regulatory hurdles related to out-of-pocket payments.
- ✓ Industrial challenges such as the limited number of companies capable of manufacturing biosimilars in Japan

### Product A anticipated timeline

	2022	2023
Product A	Application for approval (Oct)	Launch by year-end



## SULPREP

### 1H FY9/23 Summary:

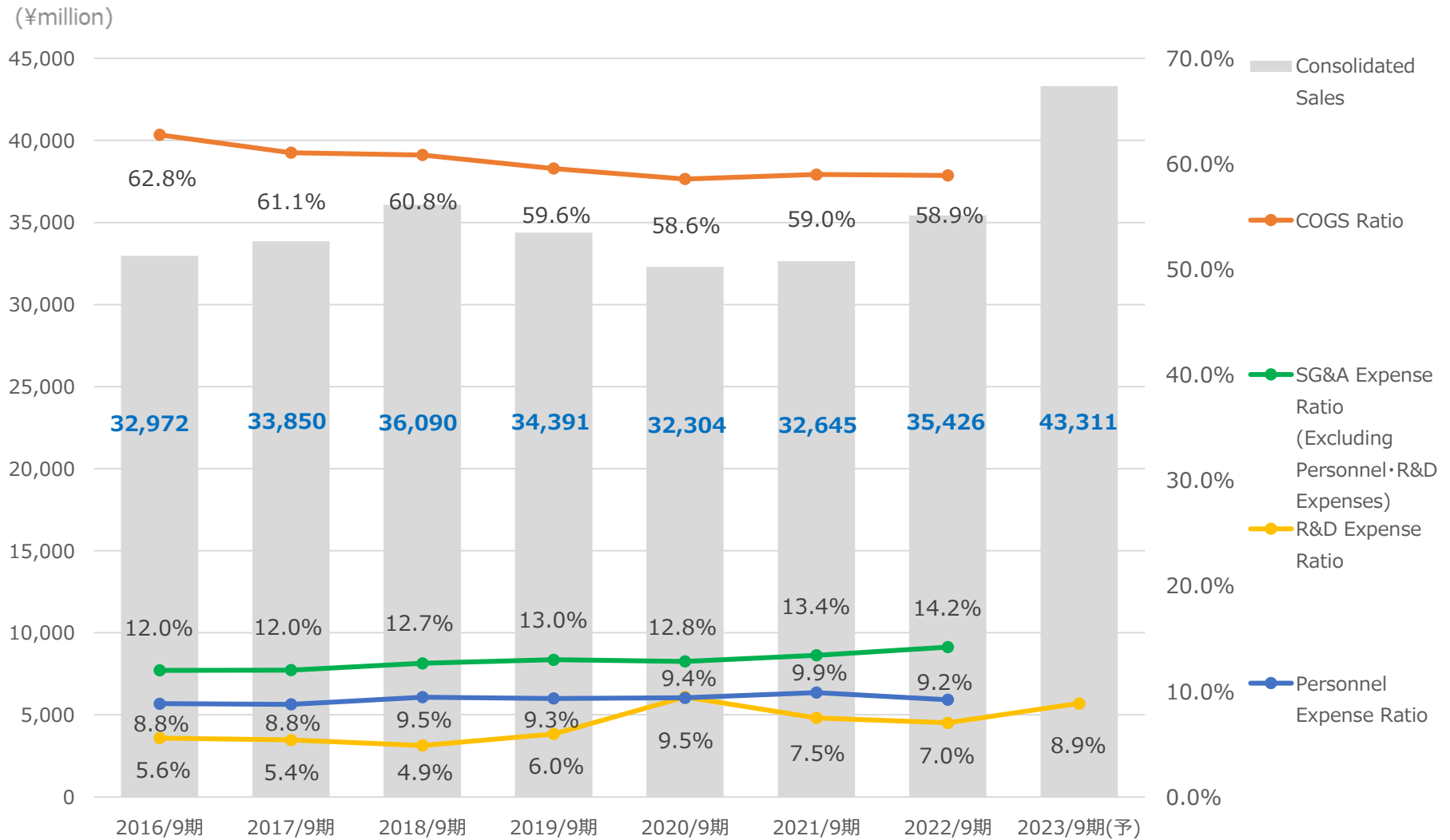
- ✓ After product acquisition in 2022, specialty MR were adopted to strengthen activities
- ✓ Number of new customer and sales are on an uptrend

### 2H FY9/23 Key Initiatives:

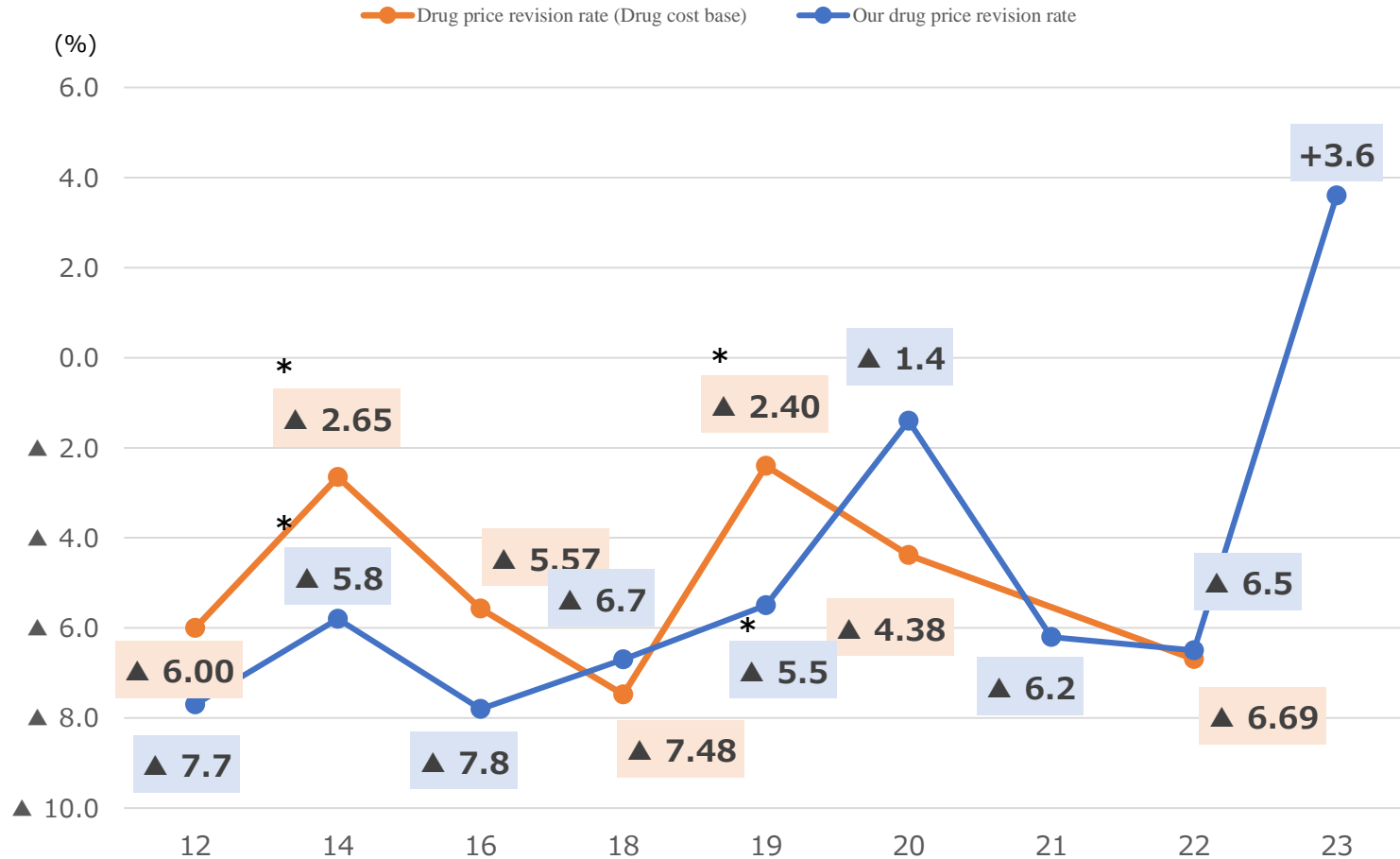
- ✓ Aiming to increase volume by appealing product value to various stakeholders of medical institutions, to reach sales target in mid-term



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



# Impact of Drug price revisions



\* : Including an increase due to consumption tax hike

## Impact of exchange rates

Type	Budget rate	Trade	Impact
USD	JPY 144.0	Purchase	3 million yen increase in cost of sales due to 1 yen depreciation
Euro	JPY 144.4	Purchase	20 million yen increase in cost of sales due to 1 yen depreciation
THB	JPY 3.8	-	14 million yen increase in profit due to 0.1 yen depreciation

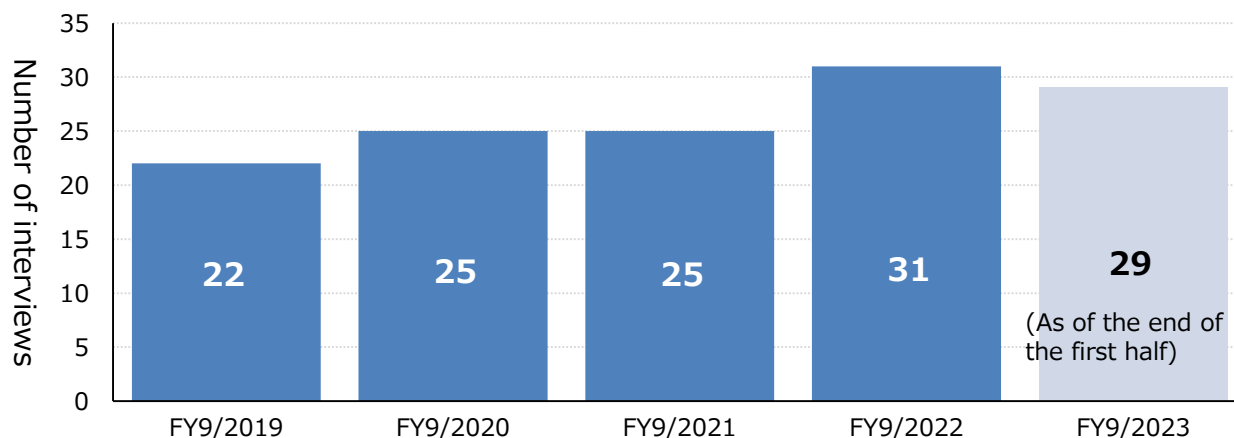
# Main products by Therapeutic Category

Hormonal drugs	Diagnostic drug	Metabolic drugs	Cellular function affecting drugs
UTROGESTAN	IOPAMIDOL	Filgrastim	DOXIL
DIENOGEST	IOHEXOL	LIMAPROST ALFADEX	ROCURONIUM
F-meno capsules			VESANOID
Favoir			
Labellefille			

Explinator	For institutional investors/analysts			For Private Investors
	Semiannual IR Meeting	Small Meeting	One-on-One	IR Session
CEO attendance	2		10	1
Others		1	13	2
<b>Total</b>	<b>2</b>	<b>1</b>	<b>23</b>	<b>3</b>

FY22/9

**Number of interviews with institutional investors and analysts  
(for each of our accounting periods)**



(As of the end of the first half)

Include small meeting participants

## Note on forecast and prospects

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

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

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

Information in this presentation about pharmaceuticals (including items in the pipeline) is not provided for the purpose of marketing or advertising or of supplying medical advice.

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