# FY9/2023 Investor Meeting Materials

November 20, 2023

Fuji Pharma Co., Ltd.

TSE:PRIME 4554

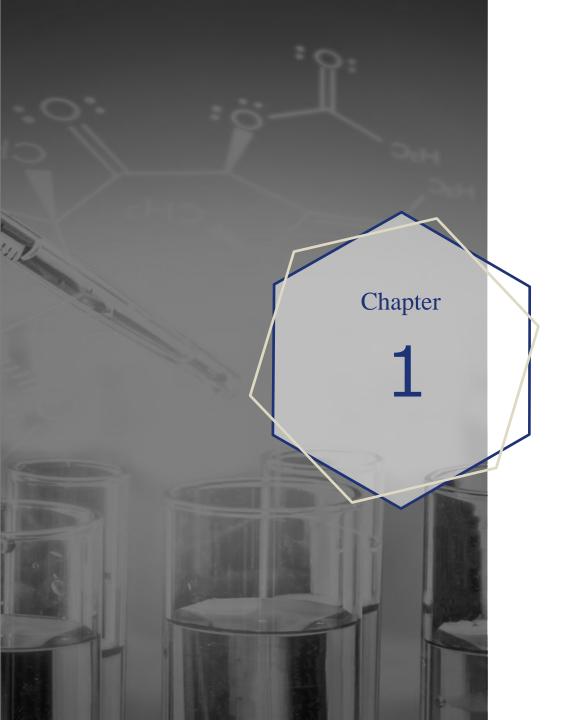




**Chapter 1 FY9/23 Consolidated Financial Results** 

**Chapter 2 FY9/24 Consolidated Forecast** 

Chapter 3 **Summary** 



# FY9/23 Consolidated Financial Results

## FY9/23 Financial Result Highlights



- Higher sales and profits due to contributions from existing/new products in Women's Healthcare
  - Net sales: + 15.4% YoY due to increase of Women's Healthcare products
  - □ Operating Profit: +2.1% YoY, Increase in sales compensated for increase in SG&A expenses and R&D expenses
- Overseas business
  - □ OLIC: Net sales + 21.0 % YoY due to increase in contracts and a weaker JPY against THB
- R&D Related Topics
  - ☐ FSN-013: [Japan] Apply for approval (October 2023)

    [Thailand] Launched (April 2023)
  - Biosimilars: Ustekinumab BS approved (September 2023)
  - New products: Transfer sales of two new drugs and medical supplement launched
     1 generic product launched and 2 generic products approved

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



Net sales: +5,463 JPY million

Due to increase of Women's Healthcare products (+15.4% YoY)

Operating Profit: +81 JPY million

Increase in sales compensated for increase in SG&A expenses and R&D expenses (+2.1% YoY)

• EBITDAR: +1,012 JPY million

(+11.6% YoY)

04-111	FY9/22	FY9/23	YoY Ch	ange	FY9/23	vs Fcst
(¥million)	Full Year	Full Year	Amount	Ratio	Forecast	Progress Ratio
Net Sales	35,426	40,889	5,463	15.4%	43,311	94.4%
Gross Profit	14,558	16,514	1,956	13.4%	-	-
Gross Margin	41.1%	40.4%	-	-	-	-
SG&A Expenses	10,781	12,656	1,875	17.4%	-	-
SG&A Margin	30.4%	31.0%	-	-		-
Operating Profit	3,777	3,858	81	2.1%	4,048	95.3%
Operating Margin	10.7%	9.4%	-	-	9.3%	-
Ordinary Profit	3,725	4,519	794	21.3%	4,088	110.5%
Ordinary Margin	10.5%	11.1%	-	-	9.4%	-
Profit Attributable to Owners of Parent	2,696	3,435	739	27.4%	2,974	115.5%
Profit Margin	7.6%	8.4%	-	-	6.9%	-
ROA	5.3%	5.6%				
ROE	7.9%	8.9%				
Net income per Share (Yen)	111.01	141.37				
Dividend payout ratio	31.5%	26.2%				
EBITDAR*1	8,738	9,750	1,012	11.6%	10,585	92.1%
EBITDA*2	6,252	6,565	313	5.0%	6,747	97.3%
Capital Expenditure	7,150	3,652	▲ 3,498	-48.9%	5,715	63.9%
Depreciation (Including Leased Equipme	2,475	2,707	232	9.4%	2,699	100.3%
R&D Expenses	2,485	3,184	699	28.1%	3,838	83.0%
R&D Expenses Ratio	7.0%	7.8%	-	-	8.9%	-

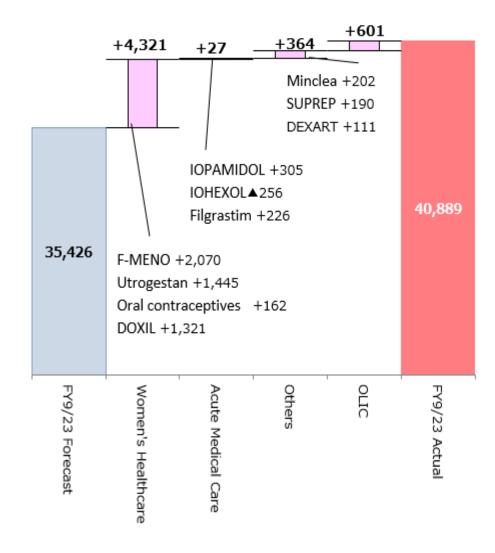
<sup>\*1)</sup> EBITDAR: Gross Profit - SG&A Expenses + Depretiation (Including Leased Equipment)+R&D Expenses

<sup>\* 2)</sup> EBITDA: Gross Profit – SG&A Expenses + Depretiation (Including Leased Equipment)

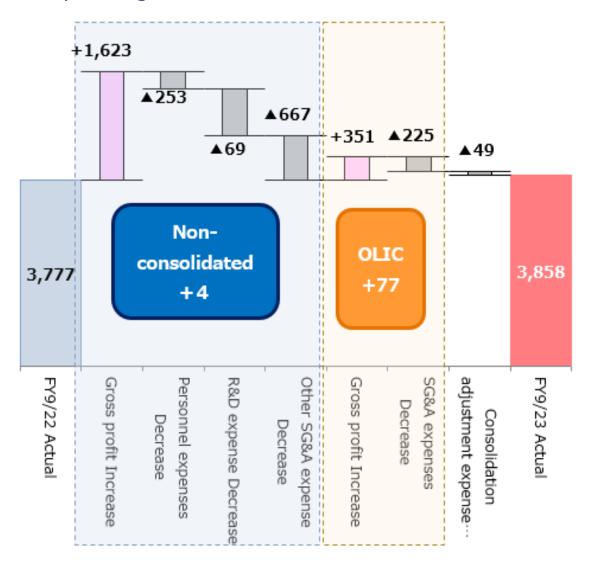
## FY9/23 Consolidated Financial Results (YoY)



Net Sales (Unit:\million)

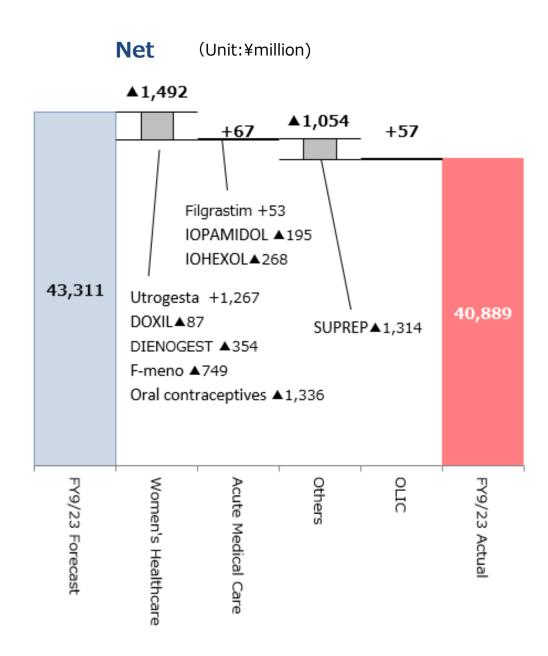


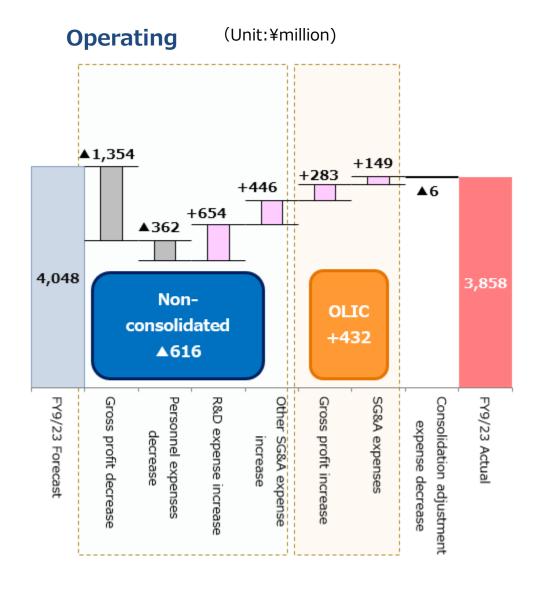
### Operating Profit (Unit:\u00e4million)



## FY9/23 Consolidated Financial Results (v. Forecast)







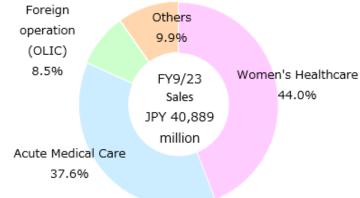
# Sales by Field



Medical Field Category	FY9/19	FY9/20	FY9/21	FY9/22	FY9/23	YoY C	hange
(¥million)	Old accounting standards	Old accounting standards	Old accounting standards	New accounting standards	New accounting standards	Amount	Ratio
Women's Healthcare	10,756	10,836	12,138	13,683	18,004	4,321	31.6%
Acute Medical Care	19,340	16,926	16,745	15,353	15,380	27	0.2%
Foreign operation (OLIC)	2,539	2,532	2,131	2,866	3,467	601	21.0%
Others	3,643	3,497	2,975	3,522	4,036	514	14.6%
Total	36,279	33,793	33,990	35,426	40,889	5,463	15.4%
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%Foreign operation (OLIC) is the amount after consolidation adjustment

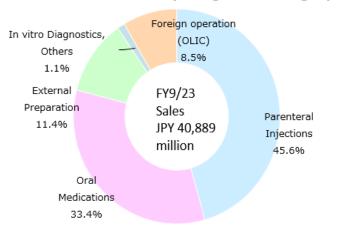
# Sales Breakdown by Medical Field



### Drug Form Category FY9/19 FY9/20 FY9/21 FY9/22 FY9/23 YoY Change Old accounting Old accounting Old accounting New accounting New accounting (¥million) Amount standards standards standards standards standards 18,643 Parenteral Injections 20,665 18,379 18,203 16,925 1,718 10.2% Oral Medications 9,729 13,641 9,799 10,456 11,978 1,663 13.9% 4,667 External Preparation 2,636 2,499 2,762 3,272 1,395 42.6% In vitro Diagnostics, Others 709 581 436 384 469 85 22.1% Foreign operation (OLIC) 2,532 3,467 601 21.0% 2,539 2,131 2,866 40,889 Total 36,279 33,793 33,990 35,426 5,463 15.4%

\*\*Foreign operation (OLIC) is the amount after consolidation adjustment

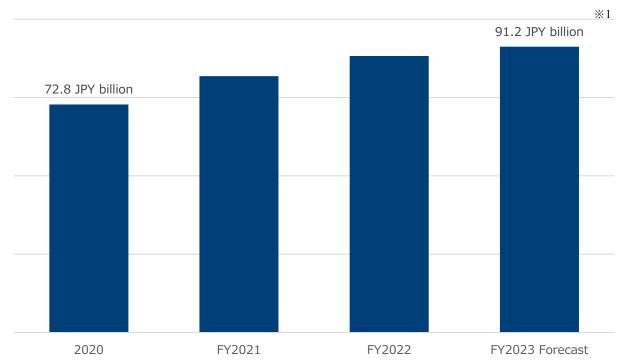
### Sales Breakdown by Drug Form Category



### Women's Healthcare



Domestic obstetrics and gynecology pharmaceutical market



Market verage growth rate \*2 7.8%

Our average growth rate

18.4%

Our share-transition \*3

**14.9%**→**19.7%** 

## **Steady Progress to Specialty Pharma in Women's Healthcare**

- Our sales \*\*3 expanded from 10.8 JPY billion in FY9/20 to 18.0 JPY billion in FY9/23.
- Expanding faster than the growth rate of the domestic obstetrics and gynecology pharmaceutical market.

<sup>※1) 20:</sup> Fuji Keizai (analysis of trends in the maternity and gynecology-related markets, which are attracting attention in insurance coverage, and future forecasts)
FY21 and beyond: Fuji Economy (2023: Trend analysis and future prediction of the obstetrics and gynecology market one year after insurance coverages)

<sup>※2)</sup> Average growth rates for slides are 2020 to 2023.

<sup>\*3)</sup> Our share trends are estimated based on our actual results.

### **Women's Healthcare and Acute Medical Care**

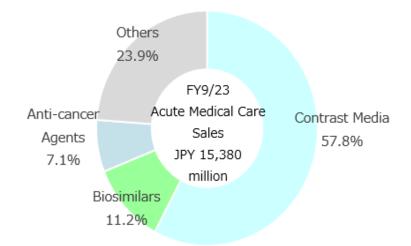


Women's Healthcare	FY9/19	FY9/20	FY9/21	FY9/22	FY9/23	YoY Ch	ange
(¥Million)	Old accounting standards	Old accounting standards	Old accounting standards	New accounting standards	New accounting standards	Amount	Ratio
Infertility Treatment drugs	3,100	2,848	3,022	3,270	4,764	1,494	45.7%
Oral Contraceptive drugs	1,909	2,542	3,180	3,685	3,848	163	4.4%
Menopausal treatment drugs	-	-	392	1,126	3,276	2,150	190.9%
Dysmenorrhea Treatment drugs	1,940	2,119	2,633	2,546	2,453	<b>▲</b> 93	-3.7%
Anti-cancer Agents	-	-	-	-	1,321	-	-
Endometriosis Treatment drugs	1,694	1,180	1,071	1,056	821	▲ 235	-22.3%
Others	2,110	2,145	1,837	1,996	1,519	<b>▲</b> 477	-23.9%
Total	10,756	10,836	12,138	13,683	18,004	4,321	31.6%

<b>Wome</b> Endome Treatmen	triosis	Others 8,4%	Net S	ales Perc	entage	
4.6%			Infertil			
				Treatment	drugs	
Anti-cancer		FY9/		26.5%	б	
Agents		Wom	en's			
7.3%		Health	ncare			
7.3%		Sal	es			
		JPY 18	3,004			
Dysmenorrhe	a	milli	ion	Oral		
Treatment	Men	opausal			. tris con	
drugs				Contracep	tive	
_	tre	atment		drugs		
13.6%	d	lrugs		21.4%	)	
	1	8.2%				

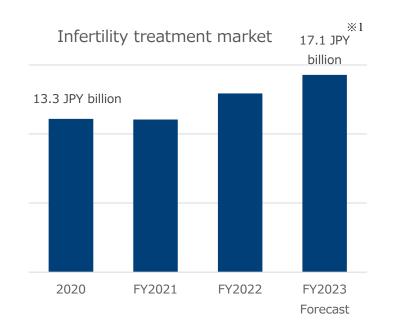
### Acute Medical Care FY9/19 FY9/20 FY9/21 FY9/22 FY9/23 New accounting Old accounting Old accounting Old accounting New accounting standards standards standards standards standards Contrast Media 11,852 9,423 9,151 8,558 8,896 338 3.9% Biosimilars 1,974 2,299 2,069 1,492 1,718 226 15.1% -17.8% Anti-cancer Agents 988 1,095 1,404 1,334 1,096 **▲** 238 Others 4,524 4,107 4,119 3,968 3,670 **▲** 298 -7.5% Total 19,340 16,926 16,745 15,353 15,380 27 0.2%

### **Acute Medical Care**



### Infertility treatment and Menopausal treatment are expanding among our Women's Healthcare





Market average growth rate \*2

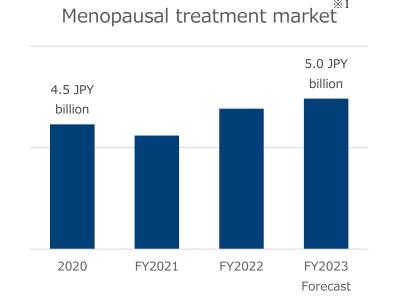
8.7%

Our average growth rate

18.7%

Our share-transition \*3

**21.4%**→**27.8%** 



Market average growth rate

3.6%

Our average growth rate

106.2%

Our share trends

**8.4%**→**65.9%** 

- Expansion of the domestic market due to the application of insurance in April 2022.
- Sales of our products increased due in part to the impact of market competition environment.
- Slight increase in domestic menopausal market.
- F-meno capsules driving Menopausal treatment market.

<sup>※1) 20:</sup> Fuji Keizai (analysis of trends in the maternity and gynecology-related markets, which are attracting attention in insurance coverage, and future forecasts)
FY21 and beyond: Fuji Economy (2023: Trend analysis and future prediction of the obstetrics and gynecology market one year after insurance coverages)

 $<sup>\</sup>ensuremath{\%2}$ ) Average growth rates for slides are 2020 to 2023.

<sup>\*3)</sup> Our share trends are estimated based on our actual results.

## 9 products of sales of top 15 are in Women's Healthcare



Product Name		FY9/19	FY9/20	FY9/21	FY9/22	FY9/23	YoY Ch	ange	FY9/	/23
(¥million)	Category	Old accounting standards	Old accounting standards	Old accounting standards	New accounting standards	New accounting standards	Amount	Ratio	Forecast	Progress Ratio
★IOPAMIDOL injection	Contrast Media	7,192	6,401	6,224	5,996	6,301	305	5.1%	6,496	97.0%
F-meno®capsules	Menopausal disorder treatment	-	=	=	681	2,751	2,070	304.0%	3,500	78.6%
◆UTROGESTAN® vaqinal capsules	Infertility treatment	788	712	889	1,218	2,663	1,445	118.6%	1,396	190.8%
Favoir® tablets	Oral contraceptive	768	1,019	1,331	1,663	1,792	129	7.8%	2,215	80.9%
DIENOGEST tablets	Endometriosis treatment	1,136	1,311	1,734	1,652	1,728	76	4.6%	2,082	83.0%
Filgrastim BS Injection Syringe	Anticancer drug treatment	1,974	2,299	2,069	1,492	1,718	226	15.1%	1,665	103.2%
★IOHEXOL injection	Contrast Media	2,287	2,172	2,088	1,707	1,451	▲ 256	-15.0%	1,719	84.4%
DOXIL® Injection	Cellular function affecting drugs	2	=	=	2	1,321	-	-	1,408	93.8%
Labellefille® tablets	Oral contraceptive	709	862	1,002	960	1,048	88	9.2%	1,769	59.2%
LEVONORGESTREL tablets	Emergency contraception	431	660	847	1,062	1,007	<b>▲</b> 55	-5.2%	1,199	84.0%
DEXART® injection	Others	894	874	961	865	976	111	12.8%	835	116.9%
FOLIAMIN® TABLETS/POWDER/INJECTION	<u>Others</u>	2	Ξ	=	475	841	366	77.1%	823	102.2%
LUNABELL® tablets (LD/ULD)	Dysmenorrhea treatment	1,583	1,045	978	955	<u>777</u>	<b>▲</b> 178	-18.6%	872	89.1%
GABAPEN® Tablets/Syrup	epilepsy treatment	-	1,104	1,092	885	<u>712</u>	<b>▲</b> 173	-19.5%	725	98.2%
BUSERELIN nasal solution	Endometriosis treatment	441	402	460	582	657	75	12.9%	627	104.8%
Total To	pp 15 Sales	18,210	18,867	19,679	20,198	25,751	5,553	27.5%	27,335	94.2%
Pct. Of	Total Sales	50.2%	55.8%	57.9%	57.0%	63.0%			63.1%	
Other Products		15,530	12,392	12,179	12,360	11,670	▲ 690	-5.6%	12,565	92.9%
Foreign operation (OLIC)		2,539	2,532	2,131	2,866	3,467	601	21.0%	3,410	101.7%
Т	otal	36,279	33,793	33,990	35,426	40,889	5,463	15.4%	43,311	94.4%
[Reference]Branded contrast media		1,245								

Acute Medical Care

Women's Healthcare

<sup>★</sup> Product name change: IOPAMIDOL injection (Former name: OYPALOMIN® injection), IOHEXOL injection (Former name: IOPAQUE® injection)

Infertility treatment drugs

<sup>\*</sup> Underlined products are the Fuji Pharma branded drugs (branded drugs, branded generic drugs (transferred products) and biosimilars)

<sup>\*</sup> Foreign operation (OLIC) is the amount after consolidation adjustment



- ASEAN
  - Net sales + 21.0 % YoY due to increase in contracts and a weaker JPY against THB
  - Nextstellis<sup>™</sup> was launched (April 2023)
- United States
  - Injection contract: FDA pre-approval inspection completion (OLIC)
  - Women's Healthcare : Development progress (Fuji)



View of Nextstellis™ Launch Events in Thailand



Injectable manufacturing plant (Fuji)



Injectable manufacturing plant (OLIC)

### **R&D-related and New product topics**



### R&D Related

■ FSN-013:[Japan] Apply for approval (October 2023)

[Thailand] Launched (April 2023)

■ Biosimilars: Ustekinumab BS approved (September 2023)

Generic: 2 products approved

### New product

■ New Drugs: Doxil ® transfer (December 2022)

Testinone Depot, acquisition (August 2023)

Medical supplement : LAFILL® Folic acid + Kestose launched (June 2023)

☐ Generic: ESTRADIOL tablets[F]launched







## FY9/23 Summary of Consolidated Balance Sheet



### Current Assets

Increase in notes and accounts receivable - trade due to increase in sales
Increase in inventory of API for stable supply

### Non-current Assets

Increase in Alvotech, Lotus in investments and other assets at market valuation

(No. of the control o	FY9/22	FY9/23	YoY Ch	ange
(¥million)	Year End	Year End	Amount	Ratio
Assets				
Current Assets	34,727	39,114	4,437	12.6%
Cash and Deposits	3,546	2,324	<b>▲</b> 1,221	-34.5%
Notes and Accounts Receivable - Trade	12,528	16,304	3,776	30.1%
Inventories	15,824	19,372	3,548	22.4%
Other	2,828	1,163	▲ 1,665	-58.9%
Non-current Assests	40,810	46,218	5,407	13.3%
Property, Plant and Equipment	18,762	20,547	1,785	9.5%
Intangible Assets	10,404	10,493	88	0.9%
Investments and Other Assets	11,643	15,177	3,534	30.4%
Total Assets	75,538	85,332	9,845	13.0%
Liabilities				
Current Liabilities	23,975	29,822	5,846	24.4%
Notes and Accounts Payable - Trade	6,249	5,672	▲ 577	-9.2%
	8,300	11,300	3,000	36.1%
	2,440	4,610	2,170	88.9%
	-	600	600	-
Other	6,986	7,639	653	9.3%
Non-current Liabilities	15,756	14,383	<b>▲</b> 1,372	-8.7%
	11,193	6,583	<b>▲</b> 4,610	-41.2%
	-	2,100	2,100	-
	4,562	5,700	1,137	24.9%
Total Liabilities	39,732	44,155	4,474	11.1%
Net Assets				
Share capital	34,175	36,723	2,547	7.5%
Capital Stock	3,799	3,799	-	0.0%
Capital Surplus	4,409	4,409	-	0.0%
Retained Earnings	26,546	29,082	2,535	9.6%
Treasury Shares	<b>▲</b> 579	▲ 567	11	-2.1%
Accumulated Other Comprehensive Income	1,627	4,451	2,823	173.6%
Total Net Assets	35,806	41,177	5,371	15.0%
Total Liabilites and Net Assets	75,538	85,332	9,845	13.0%

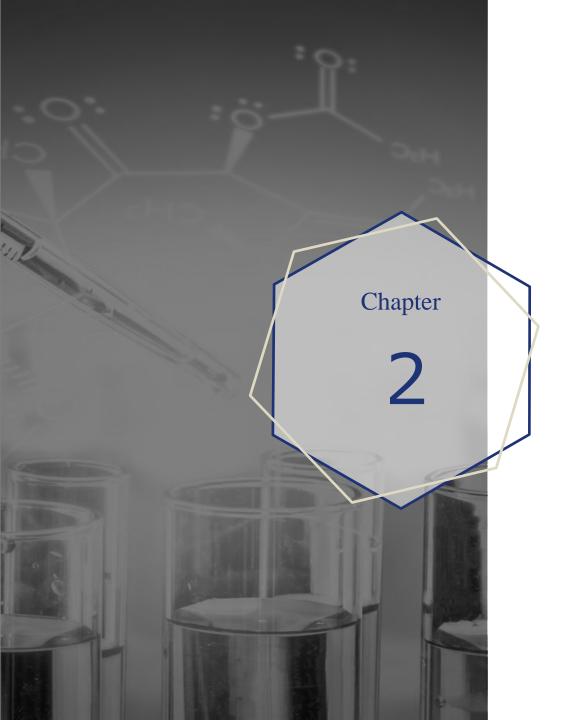
## FY9/23 Summary of Consolidated Statements of Cash Flows



- Operating CF: +2,575 JPY million
   Increase in working capital due to increase in sales
- Invested CF: +6,031 JPY million

  Marketing rights were obtained in FY9/22
- Financial CF: ▲3,179 JPY million
   Borrowing use of marketing rights in FY9/22

		14.14.01	
			-
Full Year	Full Year	Amount	Ratio
▲ 658	1,917	2,575	-391.3%
3,723	4,399	676	18.2%
2,462	2,707	245	10.0%
283	316	33	11.7%
▲ 549	▲ 3,705	<b>▲</b> 3,156	574.9%
▲ 3,618	▲ 3,395	223	-6.2%
447	▲ 652	<b>▲</b> 1,099	-245.9%
<b>▲</b> 1,498	▲ 946	552	-36.8%
<b>▲</b> 11,271	▲ 5,240	6,031	-53.5%
<b>▲</b> 5,097	<b>▲ 3,327</b>	1,770	-34.7%
<b>▲</b> 7,326	▲ 570	6,756	-92.2%
5,094	1,915	▲ 3,179	
1,300	3,000	1,700	130.8%
7,300	0	<b>▲</b> 7,300	-100.0%
▲ 2,140	<b>▲ 2,440</b>	▲ 300	14.0%
▲ 729	▲ 899	<b>▲</b> 170	23.3%
▲ 636	<b>▲ 430</b>	206	-32.4%
10,199	3,546	▲ 6,653	-65.2%
3,546	2,324	▲ 1,222	-34.5%
▲ 11,372	▲ 3,323	8,049	-70.8%
	3,723 2,462 283 ▲ 549 ▲ 3,618 447 ▲ 1,498 ▲ 11,271  ▲ 5,097 ▲ 7,326  5,094  1,300 7,300 ▲ 2,140 ▲ 729 ▲ 636 10,199 3,546	Full Year	Full Year       Amount         ▲ 658       1,917       2,575         3,723       4,399       676         2,462       2,707       245         283       316       33         ▲ 549       ▲ 3,705       ▲ 3,156         ▲ 3,618       ▲ 3,395       223         447       ▲ 652       ▲ 1,099         ▲ 1,498       ▲ 946       552         ▲ 11,271       ▲ 5,240       6,031         ▲ 5,097       ▲ 3,327       1,770         ▲ 7,326       ▲ 570       6,756         5,094       1,915       ▲ 3,179         1,300       3,000       1,700         7,300       0       ▲ 7,300         ▲ 2,140       ▲ 2,440       ▲ 300         ▲ 729       ▲ 899       ▲ 170         ▲ 636       ▲ 430       206         10,199       3,546       ▲ 6,653         3,546       2,324       ▲ 1,222





FY9/24 Consolidated Forecast

# FY9/24 Consolidated Forecast Highlights



- We plan to achieve year-on-year increases in sales and profits, mainly in the Women's Healthcare, as the culmination of Mid-Term Business Plan
  - Net Sales: Plan to achieve the Mid-Term Business Plan target (20 JPY billion) in Women's Healthcare.
  - Operating Profit: Increase in sales compensates for increase in expenses such as depreciation and R&D expenses.
  - □ Dividends: Plan to increase dividends for the third consecutive year.

### R&D Related Topics

- ☐ FSN-013: [Japan] Apply for approval
- Biosimilars: Preparing for application for 3 products
- ☐ Generic: Apply for approval for 2 products

## **FY9/24 Consolidated Forecast**



- Net sales: +8,037 billion yen
   Due to increase of Women's
   Healthcare products
   (+19.7% YoY)
- Operating Profit: +1,049 billion yen
   Increase in sales compensates for increase in expenses such as depreciation and R&D expenses (+27.2% YoY)
- **EBITDAR**: +2,088 JPY million (+21.4% YoY)

(Ymillion)	FY9/23	FY9/24	YoY Ch	nange
(¥million)	Actual	Forecast	Amount	Ratio
Net Sales	40,889	48,926	8,037	19.7%
Operating Profit	3,858	4,907	1,049	27.2%
Operating Margin	9.4%	10.0%	-	-
Ordinary Profit	4,519	5,562	1,043	23.1%
Ordinary Margin	11.1%	11.4%	-	-
Profit Attributable to Owners of Parent	3,435	4,015	580	16.9%
Profit Margin	8.4%	8.2%	-	-
ROIC*1	5.7%	7.5%		
WACC		5.0%		
EBITDAR*2	9,751	11,839	2,088	21.4%
EBITDA*3	6,566	8,768	2,202	33.5%
Capital Expenditure	3,653	5,025	1,372	37.6%
Depreciation (Inclusind Leased Equipment	2,707	3,071	364	13.4%
R&D Expenses	3,185	3,861	676	21.2%
R&D Expenses Ratio	7.8%	7.9%	-	-

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

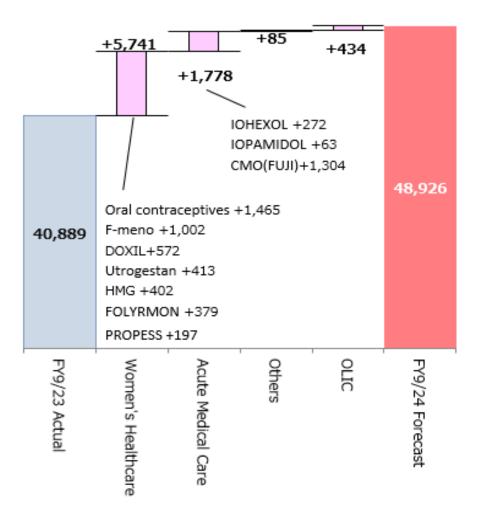
<sup>\*2)</sup> EBITDAR: Gross Profit - SG&A Expenses + Depretiation (Including Leased Equipment) + R&D Expenses

<sup>\*3)</sup> EBITDA: Gross Profit – SG&A Expenses + Depretiation (Including Leased Equipment)

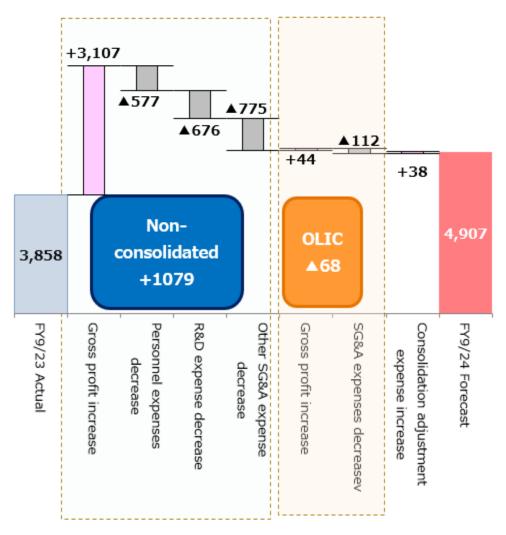
## **Summary of FY9/24 Consolidated Forecast (YoY)**



Net (Unit:\u00e4million) sales



# Operating (Unit:\u00e4million) Profit



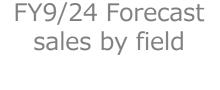
# **Sales Forecast by Field**

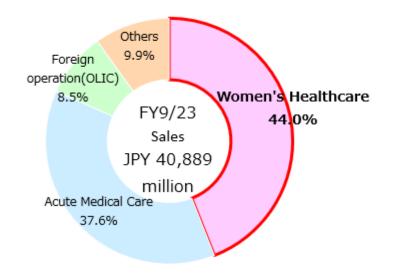


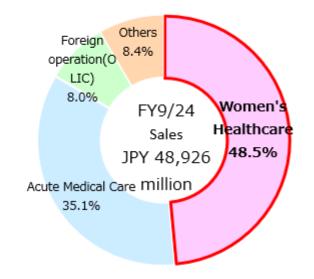
(¥million)	FY9/23	FY9/24	YoY	<b>'</b>
(#1111111011)	Actual	Forecast	Amount	Ratio
Women's Healthcare	18,004	23,745	5,741	31.9%
Acute Medical Care	15,380	17,158	1,778	11.6%
Foreign operation(OLIC)	3,467	3,901	434	12.5%
Others	4,036	4,121	85	2.1%
Total	40,889	48,926	8,037	19.7%

%Foreign operation(OLIC) is the amount after consolidation adjustment

FY9/23 sales by field

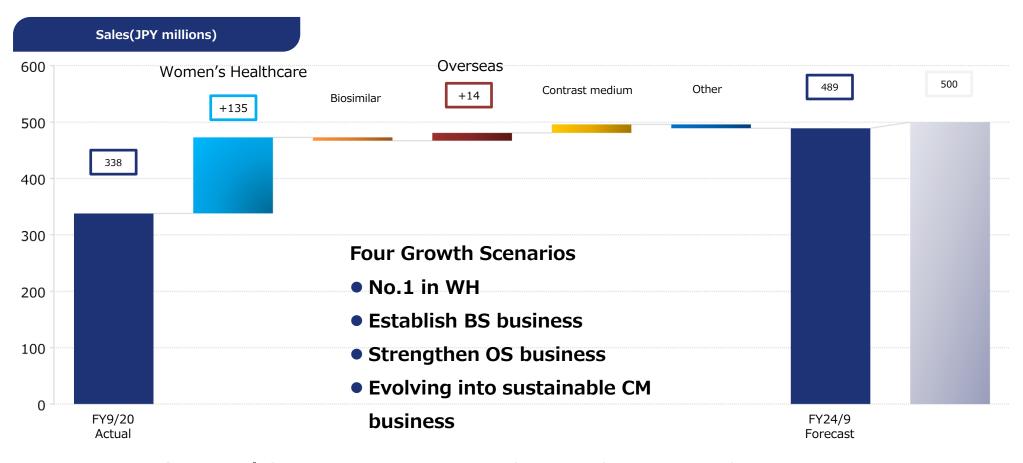






## Comparison of FY9/24 forecasts with FY9/20 results





- Women's Healthcare is expected to achieve Mid-Term Business Plan targets
- Steady implementation of expansion strategy despite some delays in plans

# FY9/24 Women's Healthcare



(Unit: billion yen, rounded down to 10 r	million yen)		2020/9	2023/9	2024/9	
Sales of six main products	Indications	situation	(Actual)	(Actual)	(Forecast)	YoY change
Levonorgestrel*	Emergency Contraceptives	Continuously expand market with generics launches and maintain volume share of over 80%	6	10	10	0
Favoir*	Oral	Top share	10	17	26	9
Labellefille*	Contraceptives	Top share	8	10	16	6
Utrogestan	Luteal Support in ART*2	Top share	7	26	30	4
Dienogest	Endometriosis Treatment	Continuous market expansion and steady growth in our market share	13	17	15	▲2
L. estrogel	Menopausal Treatment	Average growth rate 15% (20/9~23/9)	2	4	4	0
Total of 6 products			48	86	104	18
Sales of other products						
F-meno capsules	Menopausal Treatment	Strengthen sales activities	-	27	37	10
ESTRADIOL tablets	Menopausal Treatment	Launched in July 2023	-	0	6	6
Doxil	Anti-cancer drugs	Supply restrictions lifted	-	13	18	5
HMG	Infertility Treatment	Relief of supply restrictions through improving production systems	7	6	10	4
Folylmon	Infertility Treatment	Relief of supply restrictions through improving production systems	5	4	8	3
Other products			48	44	54	10
Women's Healthcare sales			108	180	237	57

<sup>\*</sup> Drug prices not listed

<sup>\*</sup> Drug prices not listed \* ART = Assisted Reproductive Technology

# **Efforts to support future growth**

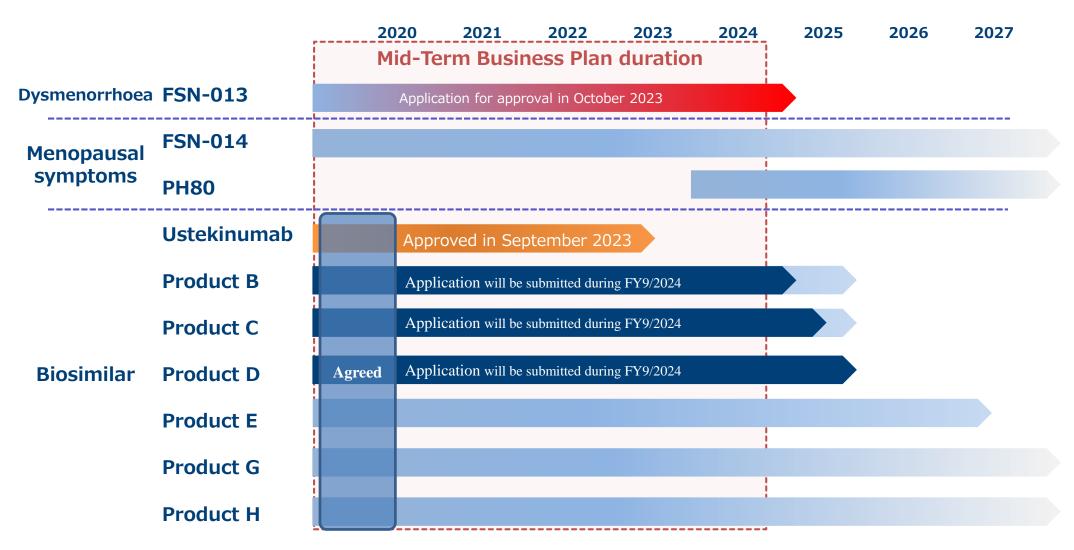


New Product Development

Overseas development

# **New Product Development (Pipeline)**





# New product development (pipeline)-Dysmenorrhea (FSN-013) ①



# **Becoming the Top-Products Supporting Our Women's Healthcare**

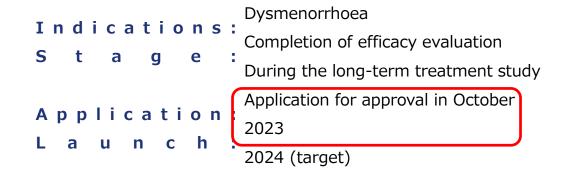
### **Overview**

- 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 37 countries including the United States and Europe (OLIC launched in Thailand in September 2023)

### 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**

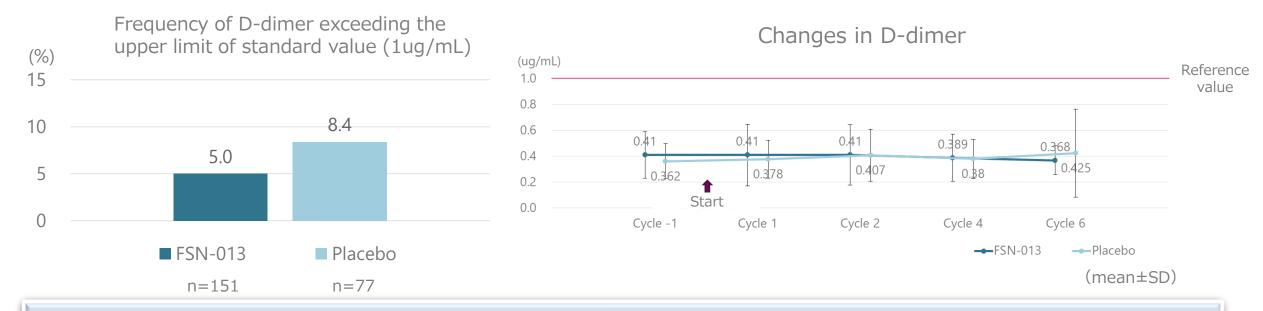


# New product development (pipeline)-Dysmenorrhea (FSN-013) ②



D-dimer test

A D-dimer is clinical useful to find out whether a patient have condition of a blood clotting disorder that is Venous thromboembolism (VTE), namely deep vein thrombosis (DVT) and pulmonary embolism (PE).



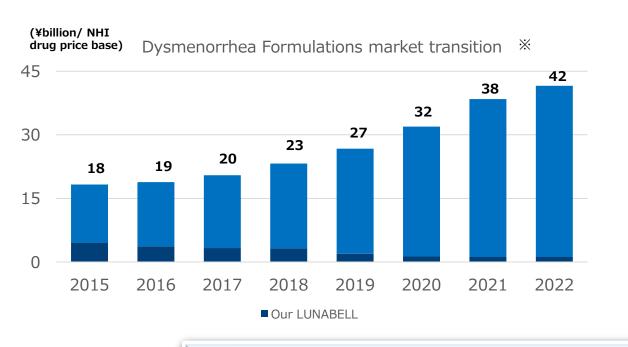
- ✓ Regarding the frequency of D-dimer exceeding the upper limit after 24 weeks of administration of FSN-013 group (active drug) and placebo group to patients with secondary dysmenorrhea, functional dysmenorrhea, and patients diagnosed with endometriosis. evaluated.
- ✓ As a result, no abnormal D-dimer value were observed in the FSN-013 administration group up to 24 weeks, and the frequency of exceeding the D-dimer reference value of 1 μg/mL(upper value) was lower in the FSN-013 group than in the placebo group.

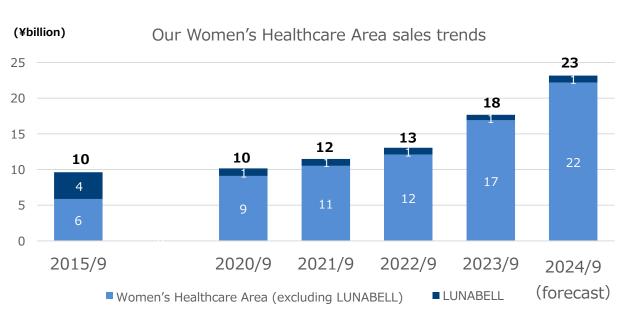
# New product development (pipeline)- Dysmenorrhea (FSN-013) 3





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.





- The market for dysmenorrhea treatment has expanded 2.3 times from 2015
- Lunabell was launched in 2008 for the treatment of dysmenorrhea, opened up the market

## New product development (pipeline)-Menopausal disorder



# Providing a wide range of treatment options for a wide variety of menopausal symptoms

Wide variety Menopausal symptoms Vasomotor symptoms (hot flashes, hot flushes, sweating, cold, etc.), psychiatric symptoms (irritability, anxiety, insomnia, depression, apathy, etc.)
Symptoms of joints etc. (low back pain, arthralgia, stiff shoulder), dizziness, tinnitus, headache, palpitations, shortness of breath, fatigue, skin symptoms (dryness, itching, eczema, etc.)

### **Issues and Needs Options** we offer L. estrogel Transdermal FSN-014 Hormone follicular hormone F-meno Capsule Lower coagulant replacement preparations Only this drug has impact compared therapy indication with existing products **ESTRADIOL** tablets Safer and more effective **Economic benefits** Wide range of options Prevention and prognosis Non-hormone PH80 replacement Hurdles to drug treatment A potential new treatment option for menopausal symptoms therapy **Supplement** Supplements for physicians

## New drug development (pipeline)-Menopause disorder (PH80)



# Potential as a New Option for Menopause Treatment.

### **Overview**

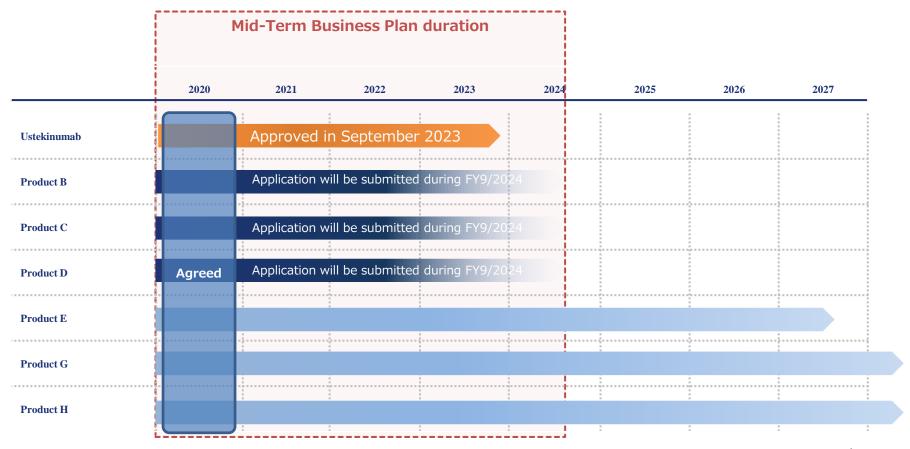
- A neuroactive pherine nasal spray product candidate being developed by Vistagen Therapeutics, Inc.
- We have entered into a time-limited (up to approximately eighteen months)
  agreement to negotiate exclusively with each other regarding a potential license to
  develop and commercialize Vistagen's PH80 in Japan.
- PH80 neuroactive nasal spray demonstrated statistically significant efficacy versus placebo in an exploratory double-blind, placebo-controlled Phase 2A study in women diagnosed with menopausal hot flashes.
- Excellent safety without the need for systemic exposure.

### **New Product Development (Pipeline)-Biosimilar**



# 7 products that have reached agreement between Fuji and Alvotech (Domestic market size: Approx. 413 JPY billion total)

- ✓ We are planning to apply for approval for 3 products in FY9/24.
- ✓ Establishment of effective information service system by establishing a specialized tissue in the field and the Medical Affairs Department.
- ✓ Our sales target in FY9/29 which is 15 JPY billion is not revised.



\*\*Time horizon is our target period
\*\*Product F: Discontinuation



### **Initiatives for FY9/24**

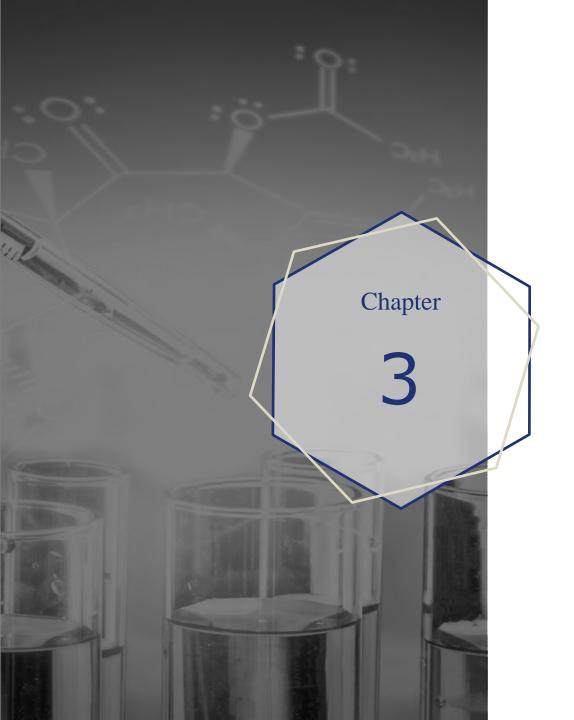
# Steady implementation of expansion strategy despite some delays in plans due to geographic and geopolitical factors

### **ASEAN: Promote business expansion**

- ✓ Nextstellis (preparing for sale in non-Thailand ASEAN countries)
- ✓ Applying for approval for 2 products, second to Nextstellis.
- ✓ In order to expand ASEAN production and sales business, a person experienced in M&A was dispatched from the head office to be in charge of strategic planning

### **United States: Supply of products for the United States**

- ✓ OLIC: CDMO business
- ✓ Fuji: Progress of Women's Healthcare product development



# Summary

## **Summary**



### Results of FY9/23

### ✓ Sales

•Our Women's Healthcare is certain to achieve Mid-Term Business Plan

### ✓ New product

- •New drug application, BS approval, and GE approval
- · Transfer sales of two new drugs, GE launched, medical supplement launched

### ✓ Overseas

- ·ASEAN: Nextstellis launched
- ·US: Progress in each project in Fuji and OLIC

### Issues of FY9/24

### ✓ Sales

•Expand sales of Women's Healthcare products and further expand sales through operation of a new pharmaceutical building

### ✓ New product

•To prepare for BS applications and expand new pipelines, including the selection of new drug candidates

### ✓ Overseas

•Expansion of OLIC production and sales business and steady progress in projects for the U.S.

### **Actions for FY9/24**

### ✓ Sales

- Strengthen Women's Healthcare sales activities
- •Stable supply through development of production system

### ✓ New product

- Preparing for launch of FSN-013
- Apply for approval of 3 BS products
- ·2 generic products launch
- •Development of Portfolio Strategy Execution System

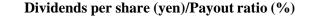
### ✓ Overseas

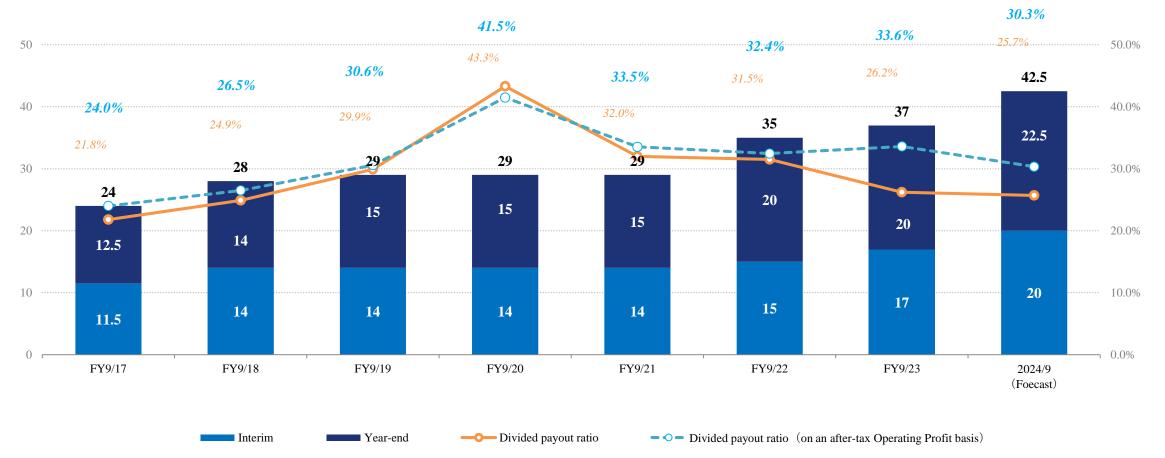
- Promote ASEAN business expansion
- •Progress in Product Supplies for the United States

### FY9/24 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 42.50 yen (interim dividend of 20 yen, year-end dividend of 22.50 yen) by applying a dividend payout ratio of 30% to the forecast for FY9/24.
- In cases where profit attributable to owners of parent fluctuates significantly due to non-recurring special factors, the amount of dividends may be determined excluding the impact of such fluctuations. (Reference: Dividend payout ratio on an after-tax Operating Profit basis in the figure below)





\* Implemented a 2-for-1 stock split on July 1, 2018Therefore, before the interim dividend for the fiscal year ended September 2018, dividends per share are calculated assuming that the stock split has been executed.



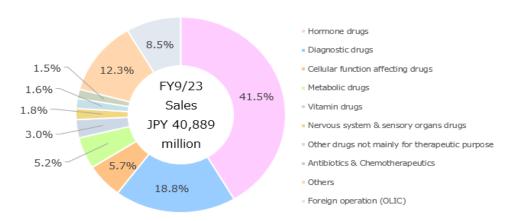
## **FY2023 Sales by Therapeutic Category**



	FY9/19	FY9/20	FY9/21	FY9/22	FY9/23	YoY Ch	ange
(¥million)	Old accounting standards	Old accounting standards	Old accounting standards	New accounting standards	New accounting standards	Amount	Ratio
Hormone drugs	10,741	10,363	11,758	13,301	16,973	3,672	27.6%
Diagnostic drugs	10,827	8,570	8,310	7,447	7,672	225	3.0%
Cellular function affecting drugs	932	966	1,002	948	2,331	1,383	145.9%
Metabolic drugs	3,074	3,216	2,917	2,318	2,136	<b>▲</b> 182	-7.9%
Vitamin drugs	407	379	401	868	1,232	364	41.9%
Nervous system & sensory organs drugs	1,099	1,200	1,170	924	749	▲ 175	-18.9%
Other drugs not mainly for therapeutic purpose	-	-	-	274	666	392	143.1%
Antibiotics & Chemotherapeutics	820	689	595	651	630	▲ 21	-3.2%
Others	5,836	5,874	5,702	5,825	5,029	▲ 796	-13.7%
Of which, CMO Business (FUJI)	2,303	2,798	3,146	3,622	3,111	▲ 511	-14.1%
Foreign operation (OLIC)	2,539	2,532	2,131	2,866	3,467	601	21.0%
Total	36,279	33,793	33,990	35,426	40,889	5,463	15.4%

%Foreign operation (OLIC) is the amount after consolidation adjustment

### Sales Breakdown by Therapeutic Category



### **Major products**

Hormones: Utrogestan, Efmeno Capsules,

Dienogest; fabowar; labelfish

Diagnostic agents: Iopamidol and iohexol

Metabolic drugs: Filgrastim

Drugs for Tissue Cell Function: Doxil Injection

# **FY2024 Sales Forecast by medicinal efficacy**



(¥million)	FY9/23	FY9/24	YoY Ch	nange
(#1111111011)	Actual	Forecast	Amount	Ratio
Hormone drugs	16,973	22,157	5,184	30.5%
Diagnostic drugs	7,672	8,001	329	4.3%
Cellular function affecting drugs	2,331	3,349	1,018	43.7%
Metabolic drugs	2,136	2,030	▲ 106	-5.0%
Other drugs not primarily intended for treatment	666	1,042	376	56.5%
Vitamin drugs	1,232	1,225	<b>▲</b> 7	-0.6%
Nervous system & sensory organs drugs	749	711	▲ 38	-5.1%
Dermatological drugs	591	593	2	0.3%
Others	5,068	5,912	844	16.6%
Including CMO Business (FUJI)	3,111	4,431	1,320	42.4%
Foreign operation(OLIC)	3,467	3,901	434	12.5%
Total	40,889	48,926	8,037	19.7%

%Foreign operation(OLIC) is the amount after consolidation adjustment

## **FY2024** Sales Forecast of Top 15 Products



Product Name	Category	FY9/23	FY9/24	Yol	
(¥million)	cutago, y	Actual	Forecast	Amount	Ratio
<b>★IOPAMIDOL Injection</b>	Contrast Media	6,301	6,364	63	1.0%
F-meno® Capsules	Menopausal disorder treatment	2,751	3,753	1,002	36.4%
◆UTROGESTAN® Vaginal Capsules	Infertility treatment	2,663	3,076	413	15.5%
Favoir® Tablets	Oral contraceptive	1,792	2,625	833	46.5%
DOXIL® Injection	Anticancer drug treatment	1,321	1,893	572	43.3%
DIENOGEST Tablets	Endometriosis treatment 1,728		1,588	<b>▲</b> 140	-8.1%
<b>★IOHEXOL Injection</b>	Contrast Media	1,451	1,723	272	18.7%
Filgrastim BS Injection Syringe	Anticancer drug treatment	1,718	1,650	<u>▲ 68</u>	-4.0%
Labellefille® Tablets	Oral contraceptive	1,048	1,602	554	52.9%
DEXART® Injection	Others	976	1,089	113	11.6%
LEVONORGESTREL Tablets	Emergency contraception	1,007	1,085	78	7.7%
◆HMG intramuscular injection	Infertility treatment	<u>652</u>	1,054	402	61.7%
LUNABELL® Tablets (LD/ULD)	<u>Dysmenorrhea treatment</u>	<u>777</u>	<u>970</u>	193	24.8%
FOLYRMON® -P Injection	Infertility treatment	485	864	379	78.1%
FOLIAMIN® TABLETS/POWDER/INJECTION	Others	<u>841</u>	<u>835</u>	<u>▲ 6</u>	-0.7%
Total To	op 15 Sales	25,518	30,178	4,660	18.3%
Pct. Of	Total Sales	62.4%	61.7%		
Other Products		11,903	14,846	2,943	24.7%
Foreign operation (OLIC)		3,467	3,901	434	12.5%
1	otal	40,889	48,926	8,037	19.7%

Acute Medical Care Women's Healthcare

<sup>★</sup>Product name change: IOPAMIDOL injection (Former name: OYPALOMIN® injection), IOHEXOL injection (Former name: IOPAQUE® injection)

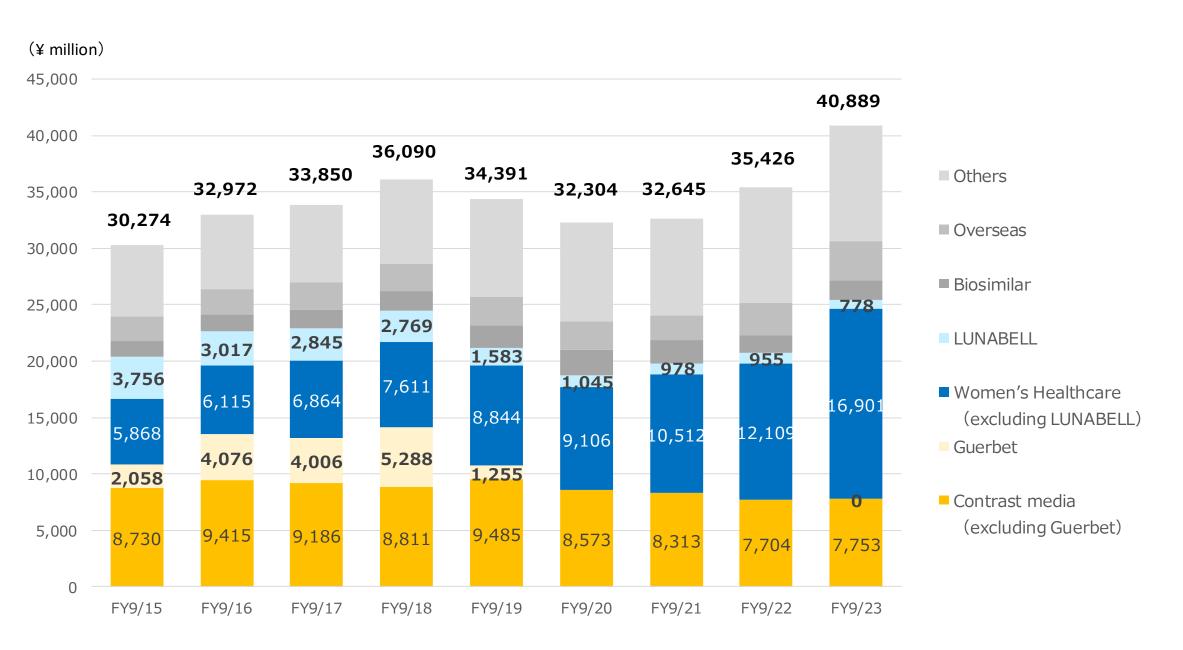
<sup>◆</sup>Infertility Treatment drugs

<sup>\*</sup> Underlined products are the Fuji Pharma branded drugs (branded drugs branded generic drugs (transferred products) and biosimilars)

<sup>\*</sup> Foreign operation(OLIC) is the amount after consolidation adjustment

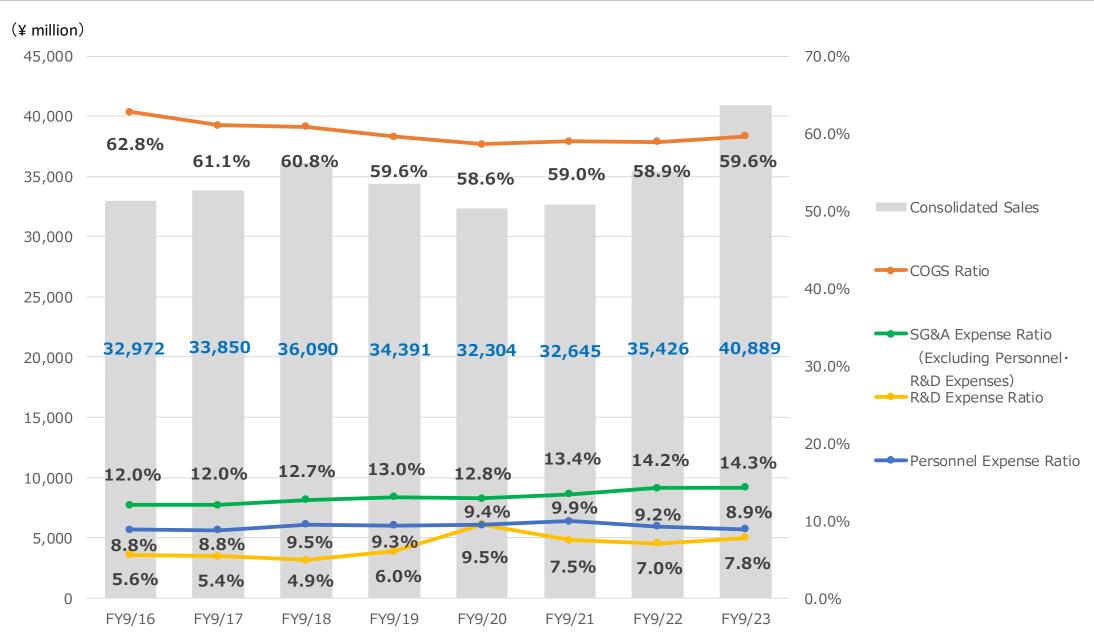
### **Sales Trends**





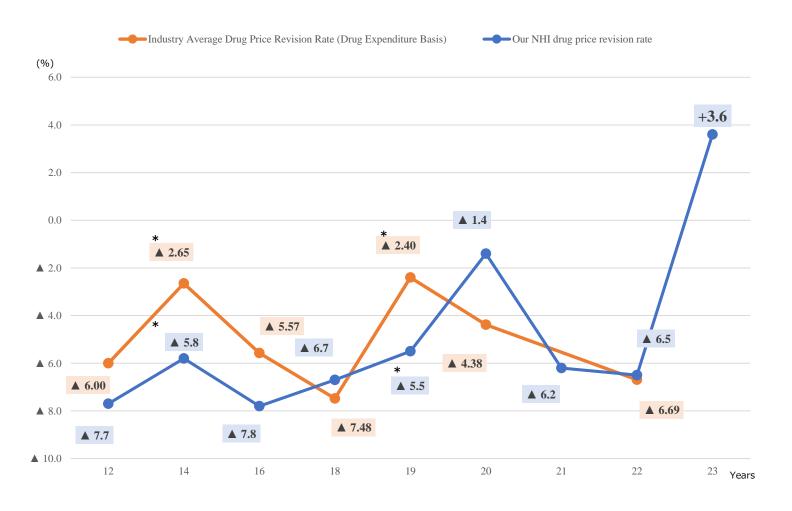
# COGS, SG&A, and R&D expenditure ratios trends (New accounting standards)





# **Impact of Drug price revisions**





\*:Including the increase due to the consumption tax hike

# **Impact of exchange rates**

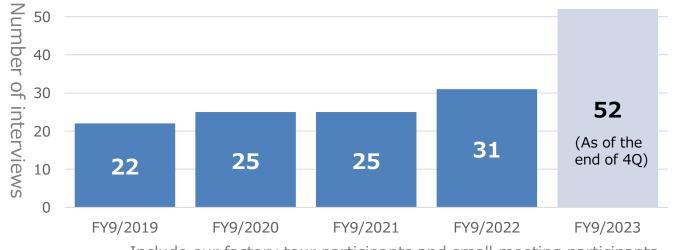


Туре	Budget rate	Trade	Impact
USD	JPY 145.0	Purchase	Increase in cost of sales by ¥5 million due to a depreciation of ¥1
Euro	JPY 155.0	Purchase	15 million yen increase in cost of sales due to 1 yen depreciation



	For institu	For Private Investors		
Explanator	Semiannual IR Meeting	Small Meeting	One-on-One	IR Session
CEO attendance	2	1	5	
Others		1	33	2
Total	2	2	38	2

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



### Note on forecast and prospects

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

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

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

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