



FujiPharma

Fuji Pharma Co., Ltd.

FY9/2022 2Q Investor Meeting

May 18, 2022

Event Summary

| | | |
|----------------------|---|--|
| [Company Name] | Fuji Pharma Co., Ltd. | |
| [Company ID] | 4554-QCODE | |
| [Event Language] | JPN | |
| [Event Type] | Earnings Announcement | |
| [Event Name] | FY9/2022 2Q Investor Meeting | |
| [Fiscal Period] | FY2022 Q2 | |
| [Date] | May 18, 2022 | |
| [Number of Pages] | 48 | |
| [Time] | 16:00 – 17:01 (Total: 61 minutes, Presentation: 50 minutes, Q&A: 11 minutes) | |
| [Venue] | Webcast | |
| [Venue Size] | | |
| [Participants] | | |
| [Number of Speakers] | 4 | |
| | Takayuki Iwai | President & CEO |
| | Atsuya Mitsunashi | Executive Corporate Officer |
| | Shuhei Morita | Executive Corporate Officer |
| | Takeshi Sato | Corporate Officer, General Manager of Corporate Planning Department |

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Presentation

Moderator: Good afternoon. Thank you for joining us today for the Fuji Pharma Co., Ltd. financial results briefing for the second quarter of the fiscal year ending September 30, 2022.

First of all, let me begin by introducing today's speakers. Mr. Takayuki Iwai, President and CEO.

Iwai: Thank you.

Moderator: Mr. Atsuya Mitsuhashi, Executive Corporate Officer.

Mitsuhashi: Thank you.

Moderator: Mr. Shuhei Morita, Executive Corporate Officer.

Morita: Thank you.

Moderator: Mr. Takeshi Sato, Corporate Officer, Corporate Planning.

Sato: Thank you.

Moderator: Now, as for today's proceedings, Mr. Sato will give an overview of the consolidated financial results for the second quarter of the fiscal year ending September 30, 2022. Mr. Iwai and Mr. Morita will discuss progress in Mid-term Business Plan.

We will then proceed to the Q&A session. We will be happy to answer as many questions as time permits, so please do not hesitate to contact us with any questions you may have. You can enter your questions in the chat at any time during the presentation.

We will now move on to the presentation of the financial results. Mr. Iwai, thank you.

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Agenda

Chapter 1 Summary of FY9/22 2Q Consolidated Financial Results

Chapter 2 Mid-Term Business Plan Progress

- Overview
- Women's Healthcare
- Biosimilar



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Iwai: Thank you very much for joining us for today's financial results briefing for the second quarter of the fiscal year ending September 30, 2022. Today, we will start with an overview of the consolidated financial results for Q2 and then discuss progress in Mid-term Business Plan.

Mr. Sato will now give an overview of the consolidated financial results for Q2.

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FY9/22 2Q Financial Result Highlights

- **Net sales and profits increase YoY contributed by new products, product acquisition, and existing women's healthcare products**
 - ▣ Net sales : +2.6% YoY due to increase of new products, product acquisition, and existing women's healthcare products
 - ▣ Operating Profit : +1.0% YoY as increase in SG&A expenses was absorbed by the increased gross profit
 - ▣ OLIC : Net sales +22.1% YoY due to an increase in new contracts
- **R&D Related topics**
 - ▣ F-meno[®] Capsules : Launched
 - ▣ Generic drugs : 2 products approved
 - ▣ FSN-013 : Phase III in process as planned



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Sato: This is Sato from Corporate Planning. Thank you. I would like to discuss the consolidated financial summary for the second quarter of the fiscal year ending September 30, 2022.

In the first half of the fiscal year ending September 30, 2022, net sales and profits increased due to contributions from new products such as F-meno, acquisition products and in-licensed products such as PROPESS, and existing women's healthcare products, including oral contraceptives.

Changes in the cost structure due to changes in the product mix resulted in an increase in gross margin. This absorbed the increase in SG&A expenses due to R&D and other expenses.

In OLIC, net sales increased due to an increase in new contracts. However, profits were at the same level as the previous fiscal year due to an increase in SG&A expenses, including up-front costs for production and sales.

Topics in the first half of the year related to R&D included the launch of F-meno capsules, which were approved at the end of the previous fiscal year, and the approval of two new generic products.

The Phase III clinical trials of FSN-013 is progressing as planned.

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Summary of FY9/22 2Q Consolidated Financial Results

- Net sales : +449 JPY million (+2.6% YoY) - Increase of new products, product acquisition, and existing women's healthcare products
- Operating profit : +26 JPY million (+1.0% YoY) - Increase in SG&A and R&D expenses was absorbed by the increased gross profit
- Profit attributable to owners of parent : ▲187 JPY million (▲9.3% YoY) - Sold cross-shareholdings in the previous fiscal year (153 JPY million)

| | | reference | | | | | | | |
|---|-----------------------------|-----------------------------|-----------------------------|--|--------|----------------------------------|----------------------|-----------------------------|-------------------|
| (¥million) | FY9/21 First half | FY9/21 First half | FY9/22 First half | YoY Change (Old accounting standards) | | FY9/22 First half Forecast | vs Fcst | FY9/22 Forecast | vs Fcst |
| | Old accounting standards | New accounting standards | New accounting standards | Amount | Ratio | New accounting standards | Achievement Ratio | New accounting standards | Progress Ratio |
| Net Sales | 17,277 | 16,511 | 17,726 | 449 | 2.6% | 17,473 | 101.4% | 35,966 | 49.3% |
| Gross Profit | 7,664 | 6,897 | 7,675 | 11 | 0.1% | - | - | - | - |
| Gross Margin | 44.4% | 41.8% | 43.3% | - | - | - | - | - | - |
| SG&A Expenses | 4,977 | 4,211 | 4,963 | ▲ 14 | -0.3% | - | - | - | - |
| SG&A Margin | 28.8% | 25.5% | 28.0% | - | - | - | - | - | - |
| Operating Profit | 2,686 | 2,686 | 2,712 | 26 | 1.0% | 1,643 | 165.1% | 3,490 | 77.7% |
| Operating Margin | 15.5% | 16.3% | 15.3% | - | - | 9.4% | - | 9.7% | - |
| Ordinary Profit | 2,738 | 2,738 | 2,866 | 128 | 4.7% | 1,668 | 171.8% | 3,540 | 81.0% |
| Ordinary Margin | 15.8% | 16.6% | 16.2% | - | - | 9.5% | - | 9.8% | - |
| Profit Attributable to Owners of Parent | 2,021 | 2,021 | 1,834 | ▲ 187 | -9.3% | 1,211 | 151.4% | 2,562 | 71.6% |
| Profit Margin | 11.7% | 12.2% | 10.3% | - | - | 6.9% | - | 7.1% | - |
| EBITDAR* ¹ | 4,563 | 4,563 | 4,974 | 411 | 9.0% | | | 8,059 | 61.7% |
| EBITDA* ² | 3,701 | 3,701 | 3,822 | 121 | 3.3% | | | 5,250 | 72.8% |
| Capital Expenditure | 1,567 | 1,567 | 3,449 | 1,882 | 120.1% | | | 7,172 | 48.1% |
| Depreciation (Including Leased Equipment) | 1,015 | 1,015 | 1,109 | 94 | 9.3% | | | 1,760 | 63.0% |
| R&D Expenses | 861 | 861 | 1,152 | 291 | 33.8% | | | 2,809 | 41.0% |
| R&D Expenses Ratio | 5.0% | 5.2% | 6.5% | - | - | | | 7.8% | - |

* 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)

※ From the beginning of FY9/22, to apply "The Accounting Standards for Recognizing Revenues" (corporate accounting standard No. 29), the above-mentioned FY9/22 first half consolidated financial results and FY9/22 first half consolidated forecast and FY9/22 consolidated forecast are the figure after the application of new accounting standards.



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I will add a few additional points that were not covered on the general summary on the previous slide.

First, while operating and ordinary profit increased, profit attributable to owners of parent decreased. This was due to the sale of cross-shareholdings of approximately JPY150 million recorded in the previous fiscal year, and the resulting temporary difference in tax effect accounting related to the provision in the previous fiscal year.

Next, R&D expenses increased approximately JPY300 million from the previous year. In terms of R&D expenses as a percentage of net sales, this represented a 1.5% increase.

Due to postponement of R&D expenses and the transition of acquisition and in-licensed products, cumulative operating profit to the second quarter increased significantly. For the full year, we will continue to aim to exceed the plan, but at this point, we believe that the results will be generally in line with the plan.

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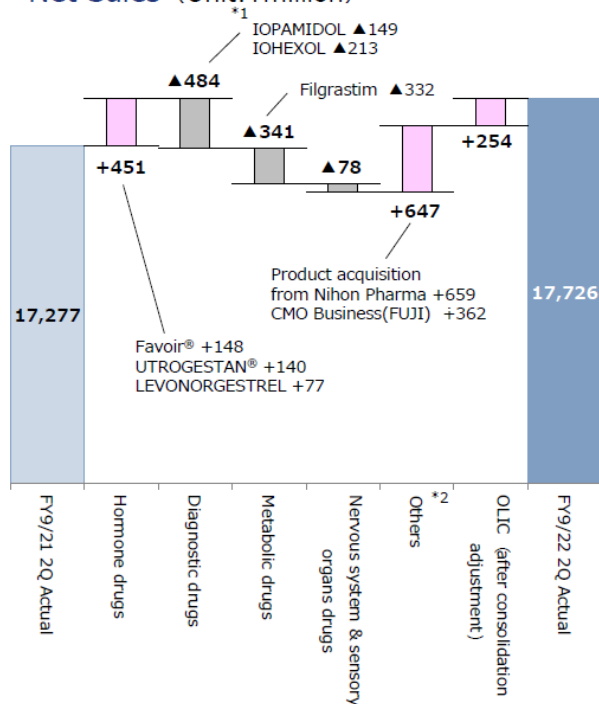
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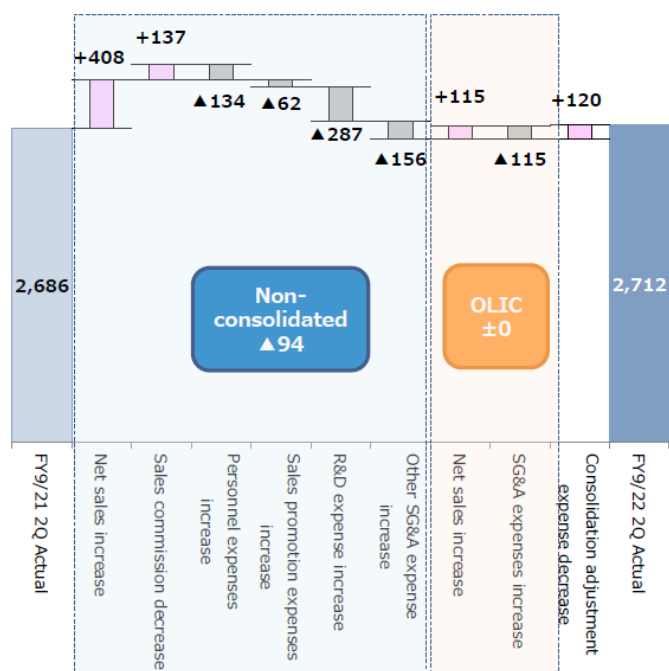
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Summary of FY9/22 2Q Consolidated Financial Results (YoY)

Net Sales (Unit:¥million)



Operating Profit (Unit:¥million)



※ From the beginning of FY9/22, to apply "The Accounting Standards for Recognizing Revenues" (corporate accounting standard No. 29), the above-mentioned FY9/22 first half consolidated financial results is the figure after the application of new accounting standards. Therefore, the waterfall chart of Net sales is for reference only.



*1) Product name change : IOPAMIDOL injection (Former name : OYPALOMIN® injection) , IOHEXOL injection (Former name : IOPAQUE® injection)
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*2) OLIC : Our subsidiary CMO company (Head office and plant in Thailand)

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Here is a comparison of sales and operating profit compared to the previous fiscal year.

In terms of sales, we saw increased sales in hormone drugs, Nihon Pharmaceutical acquisition products, contracts at the Toyama Factory, and OLIC. On the other hand, sales of contrast media and filgrastim decreased due to the NHI price revision and other factors. Overall, sales increased.

Operating profit increased due to an increase in gross profit from higher revenues, which offset increases in personnel expenses, R&D expenses, and other expenses.

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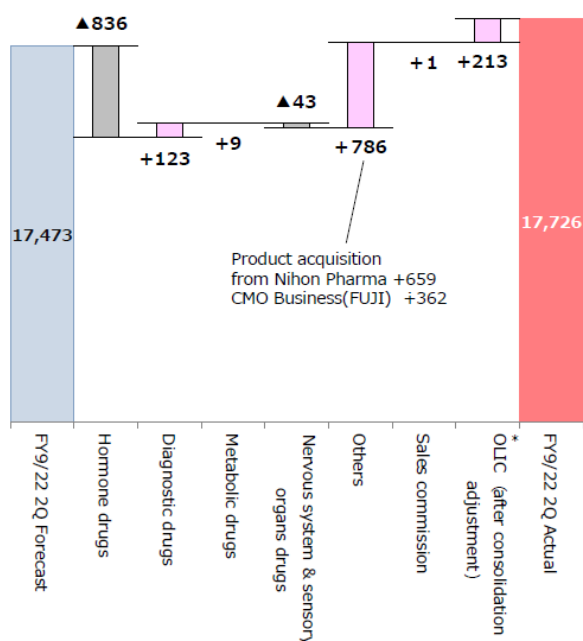
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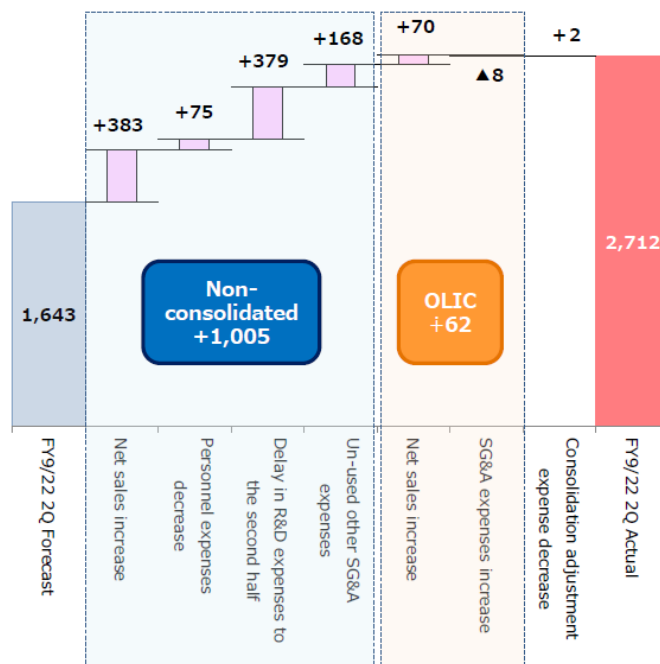


Summary of FY9/22 2Q Consolidated Financial Results (v. Forecast)

Net Sales (Unit:¥million)



Operating Profit (Unit:¥million)



※ From the beginning of FY9/22, to apply "The Accounting Standards for Recognizing Revenues" (corporate accounting standard No. 29), the above-mentioned FY9/22 first half consolidated financial results is the figure after the application of new accounting standards. Therefore, the waterfall chart of Net sales is for reference only.



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

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Here is a comparison of sales and operating profit versus forecast.

Sales fell short for hormone drugs which are valuable treatments for women's healthcare and for which we had some degree of expectation. However, sales of acquisition products that were expected in the second half of the year were shifted to the first half of the year. Also, the strong performance of OLIC also contributed to higher sales than expected.

Operating profit significantly exceeded the forecast due to an increase in gross profit from higher sales, curbing of SG&A expenses, and the postponement of R&D expenses to a later date.

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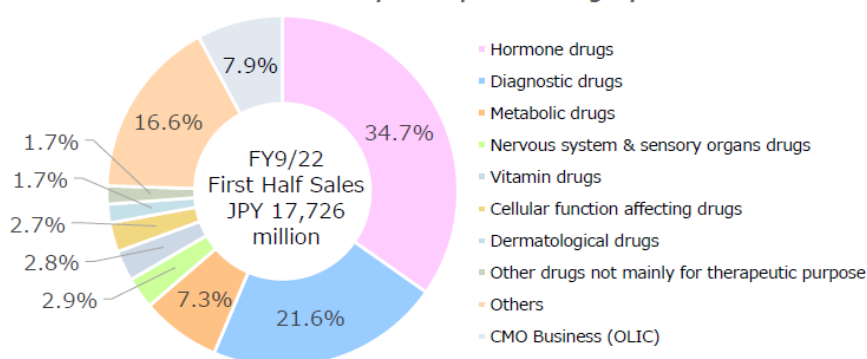
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Sales by Therapeutic Category

| (\$million) | FY9/18 First half | FY9/19 First half | FY9/20 First half | FY9/21 First half | FY9/22 First half | YoY Change | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|------------|-------------|
| | Old accounting standards | Old accounting standards | Old accounting standards | Old accounting standards | New accounting standards | Amount | Ratio |
| Hormone drugs | 5,290 | 5,278 | 5,053 | 5,707 | 6,158 | 451 | 7.9% |
| Diagnostic drugs | 6,323 | 6,028 | 4,456 | 4,315 | 3,831 | ▲ 484 | -11.2% |
| Metabolic drugs | 1,442 | 1,505 | 1,572 | 1,640 | 1,299 | ▲ 341 | -20.8% |
| Nervous system & sensory organs drugs | 82 | 449 | 593 | 593 | 515 | ▲ 78 | -13.2% |
| Vitamin drugs | 193 | 206 | 180 | 197 | 499 | 302 | 153.3% |
| Cellular function affecting drugs | 393 | 461 | 476 | 491 | 476 | ▲ 15 | -3.1% |
| Dermatological drugs | 198 | 265 | 277 | 288 | 305 | 17 | 5.9% |
| Other drugs not mainly for therapeutic purpose | - | - | - | - | 296 | - | - |
| Others | 2,744 | 3,102 | 3,004 | 2,893 | 2,939 | 46 | 1.6% |
| Of which, CMO Business (FUJI) | 643 | 1,126 | 1,269 | 1,501 | 1,863 | 362 | 24.1% |
| CMO Business (OLIC) | 1,293 | 1,186 | 1,290 | 1,149 | 1,403 | 254 | 22.1% |
| Total | 17,961 | 18,483 | 16,905 | 17,277 | 17,726 | 449 | 2.6% |

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

Sales Breakdown by Therapeutic Category



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※ From the beginning of FY9/22, to apply "The Accounting Standards for Recognizing Revenues" (corporate accounting standard No. 29), the above-mentioned FY9/22 first half sales by therapeutic category is the figure after the application of new accounting standards. Therefore, YoY changes (in amount and ratio) are for reference only.

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Sales by drug class are shown here.

Sales of hormone drugs have grown significantly and now account for more than one-third of our sales. The total sales from the Toyama factory and OLIC accounts for approximately 20% of the total, and the percentage is increasing every year.

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Sales of Top 15 Products

| Product Name (¥million) | Therapeutic Category | FY9/18 First half | FY9/19 First half | FY9/20 First half | FY9/21 First half | FY9/22 First half | YoY Change (Old accounting standards) | | FY9/22 | |
|------------------------------------|--|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|--|--------|----------|-------------------|
| | | Old accounting standards | Old accounting standards | Old accounting standards | Old accounting standards | New accounting standards | Amount | Ratio | Forecast | Progress Ratio |
| ★IOPAMIDOL injection | Diagnostic drugs | 2,947 | 3,580 | 3,342 | 3,206 | 3,057 | ▲ 149 | -4.6% | 5,829 | 52.4% |
| ★IOHEXOL injection | Diagnostic drugs | 910 | 1,115 | 1,116 | 1,109 | 896 | ▲ 213 | -19.2% | 1,703 | 52.6% |
| Filgrastim BS Injection Syringe | Metabolic drugs | 847 | 945 | 1,097 | 1,212 | 880 | ▲ 332 | -27.4% | 1,784 | 49.3% |
| DIENOGEST tablets | Hormone drugs | 373 | 532 | 596 | 830 | 812 | ▲ 18 | -2.2% | 1,741 | 46.6% |
| Favoi® tablets | Hormone drugs | 335 | 328 | 464 | 601 | 749 | 148 | 24.6% | 1,541 | 48.6% |
| ◆UTROGESTAN® vaginal capsules | Hormone drugs | 298 | 332 | 350 | 442 | 582 | 140 | 31.7% | 1,093 | 53.2% |
| Labellefil® tablets | Hormone drugs | 223 | 316 | 393 | 497 | 500 | 3 | 0.6% | 1,294 | 38.6% |
| GABAPEN® Tablets | Nervous system & sensory organs drugs | - | - | 543 | 538 | 497 | ▲ 41 | -7.6% | 1,107 | 44.9% |
| LUNABELL® tablets (LD/ULD) | Hormone drugs | 1,289 | 978 | 534 | 472 | 470 | ▲ 2 | -0.4% | 767 | 61.3% |
| LEVONORGESTREL tablets | Hormone drugs | - | 47 | 326 | 370 | 447 | 77 | 20.8% | 857 | 52.2% |
| DEXART® injection | Hormone drugs | 431 | 435 | 434 | 445 | 418 | ▲ 27 | -6.1% | 898 | 46.5% |
| ◆HMG intramuscular injection | Hormone drugs | 447 | 400 | 365 | 399 | 406 | 7 | 1.8% | 675 | 60.1% |
| FOLIAMIN® | Vitamin drugs | - | - | - | - | 304 | - | - | - | - |
| BUSERELIN nasal solution | Hormone drugs | 215 | 218 | 202 | 216 | 252 | 36 | 16.7% | 457 | 55.1% |
| ◆POLYRMON® -P injection | Hormone drugs | 304 | 316 | 286 | 295 | 250 | ▲ 45 | -15.3% | 633 | 39.5% |
| Total Top 15 Sales | | 8,618 | 9,542 | 10,051 | 10,638 | 10,527 | ▲ 111 | -1.0% | 20,386 | 51.6% |
| Pct. Of Total Sales | | 48.0% | 51.6% | 59.5% | 61.6% | 59.4% | | | 56.7% | |
| Other Products | | 8,049 | 7,754 | 5,563 | 5,489 | 5,795 | 306 | 5.6% | 13,121 | 44.2% |
| CMO Business (OLIC) | | 1,293 | 1,186 | 1,290 | 1,149 | 1,403 | 254 | 22.1% | 2,457 | 57.1% |
| Total | | 17,961 | 18,483 | 16,905 | 17,277 | 17,726 | 449 | 2.6% | 35,966 | 49.3% |
| [Reference] Branded contrast media | | 2,316 | 1,245 | 0 | 0 | 0 | | | | |
| Acute Medical Care | Women's Healthcare | | | | | | | | | |

※ From the beginning of FY9/22, to apply "The Accounting Standards for Recognizing Revenues" (corporate accounting standard No. 29), the above-mentioned FY9/22 first half sales of Top 15 products and FY9/22 forecast are the figure after the application of new accounting standards. Therefore, YoY changes (in amount and ratio) are for reference only.



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Here are sales figures for the top 15 products.

FOLIAMIN is a new addition to the Nihon Pharmaceutical acquisition products.

The percentage of progress toward the full-year forecast was approximately 50% overall, almost in line with our plan. However, we do see some variability by product. In the second half of the year, we intend to further strengthen our activities to achieve our full-year forecast.

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Sales by Medical Field and Drug Form Category

| Medical Field Category (¥million) | FY9/18 First half Old accounting standards | 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 | YoY Change (Old accounting standards) | |
|--------------------------------------|---|---|---|---|---|--|-------|
| | | | | | | Amount | Ratio |
| Acute Medical Care | 9,980 | 10,347 | 8,414 | 8,584 | 7,989 | ▲ 595 | -6.9% |
| Women's Healthcare | 5,222 | 5,154 | 5,316 | 5,896 | 6,384 | 488 | 8.3% |
| Others | 1,464 | 1,795 | 1,884 | 1,646 | 1,949 | 303 | 18.4% |
| CMO Business (OLIC) | 1,293 | 1,186 | 1,290 | 1,149 | 1,403 | 254 | 22.1% |
| Total | 17,961 | 18,483 | 16,905 | 17,277 | 17,726 | 449 | 2.6% |

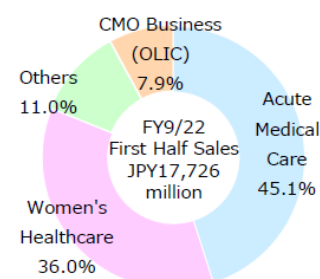
※CMO Business (OLIC) is the amount after consolidation adjustment

| Drug Form Category (¥million) | FY9/18 First half Old accounting standards | 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 | YoY Change (Old accounting standards) | |
|----------------------------------|---|---|---|---|---|--|--------|
| | | | | | | Amount | Ratio |
| Parenteral Injections | 10,617 | 10,998 | 9,157 | 9,362 | 8,777 | ▲ 585 | -6.2% |
| Oral Medications | 4,362 | 4,614 | 4,796 | 5,065 | 5,299 | 234 | 4.6% |
| External Preparation | 1,104 | 1,238 | 1,251 | 1,383 | 1,545 | 162 | 11.7% |
| In vitro Diagnostics, Others | 583 | 445 | 409 | 316 | 700 | 384 | 121.5% |
| CMO Business (OLIC) | 1,293 | 1,186 | 1,290 | 1,149 | 1,403 | 254 | 22.1% |
| Total | 17,961 | 18,483 | 16,905 | 17,277 | 17,726 | 449 | 2.6% |

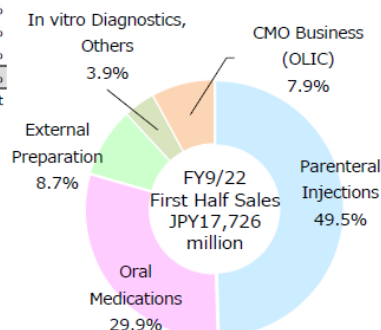
※CMO Business (OLIC) is the amount after consolidation adjustment

※ From the beginning of FY9/22, to apply "The Accounting Standards for Recognizing Revenues" (corporate accounting standard No. 29), the above-mentioned FY9/22 first half sales by Medical Field and Drug Form Category are the figure after the application of new accounting standards.
Therefore, YoY changes(in amount and ratio) are for reference only.

Sales Breakdown by Medical Field



Sales Breakdown by Drug Form Category



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Sales trends by medical field and dosage form are shown in the table below.

There is no significant change in the trend in acute medical care and women's healthcare or parenteral injections and oral medications.

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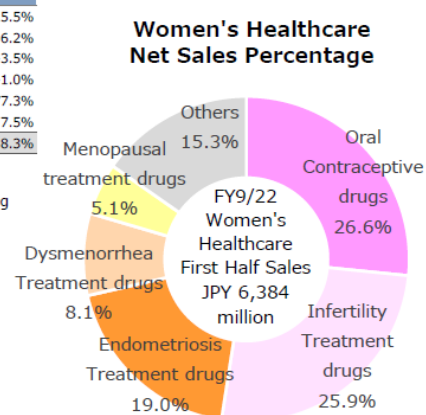
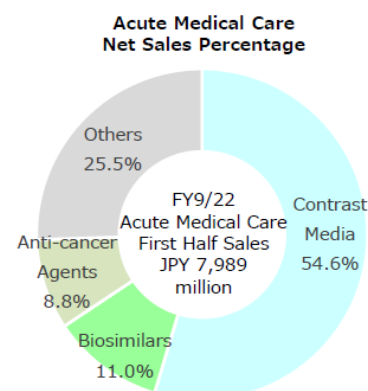


Sales of Acute Medical Care and Women's Healthcare

| Acute Medical Care (¥Million) | FY9/18 First half Old accounting standards | 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 | YoY Change (Old accounting standards) | |
|----------------------------------|---|---|---|---|---|--|--------------|
| | | | | | | Amount | Ratio |
| Contrast Media | 6,194 | 6,661 | 4,796 | 4,718 | 4,364 | ▲ 354 | -7.5% |
| Biosimilars | 847 | 945 | 1,097 | 1,212 | 880 | ▲ 332 | -27.4% |
| Anti-cancer Agents | 462 | 410 | 457 | 597 | 706 | 109 | 18.3% |
| Others | 2,476 | 2,329 | 2,062 | 2,056 | 2,037 | ▲ 19 | -0.9% |
| Total | 9,980 | 10,347 | 8,414 | 8,584 | 7,989 | ▲ 595 | -6.9% |

| Women's Healthcare (¥Million) | FY9/18 First half Old accounting standards | 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 | YoY Change (Old accounting standards) | |
|----------------------------------|---|---|---|---|---|--|-------------|
| | | | | | | Amount | Ratio |
| Oral Contraceptive drugs | 557 | 644 | 1,183 | 1,469 | 1,697 | 228 | 15.5% |
| Infertility Treatment drugs | 1,468 | 1,475 | 1,411 | 1,553 | 1,650 | 97 | 6.2% |
| Endometriosis Treatment drugs | 741 | 915 | 1,012 | 1,255 | 1,211 | ▲ 44 | -3.5% |
| Dysmenorrhea Treatment drugs | 1,435 | 1,030 | 602 | 524 | 519 | ▲ 5 | -1.0% |
| Menopausal treatment drugs | 139 | 154 | 167 | 185 | 328 | 143 | 77.3% |
| Others | 880 | 933 | 937 | 908 | 976 | 68 | 7.5% |
| Total | 5,222 | 5,154 | 5,316 | 5,896 | 6,384 | 488 | 8.3% |

※ From the beginning of FY9/22, to apply "The Accounting Standards for Recognizing Revenues" (corporate accounting standard No. 29), the above-mentioned FY9/22 first half Sales of Acute Medical Care Women's Healthcare are the figure after the application of new accounting standards.
Therefore, YoY changes(in amount and ratio) are for reference only.



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The sales trends for acute medical care and women's healthcare are shown in the table below.

In the area of women's healthcare, with the launch of F-meno capsules, sales of menopausal treatment drugs now accounts for about 5% of total sales in the category.

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FY9/22 2Q Summary of Consolidated Balance Sheet

| (¥million) | FY9/21 | FY9/22 | YoY Change | |
|---|---------------|---------------|---------------|--------------|
| | Year End | End of 2Q | Amount | Ratio |
| Assets | | | | |
| Current Assets | 34,834 | 33,510 | ▲ 1,324 | -3.8% |
| Cash and Deposits | 10,199 | 5,975 | ▲ 4,224 | -41.4% |
| Notes and Accounts Receivable - Trade | 11,866 | 12,393 | 527 | 4.4% |
| Inventories | 12,007 | 13,392 | 1,385 | 11.5% |
| Other | 761 | 1,747 | 986 | 129.6% |
| Non-current Assets | 29,404 | 40,788 | 11,384 | 38.7% |
| Property, Plant and Equipment | 14,392 | 17,467 | 3,075 | 21.4% |
| Intangible Assets | 2,397 | 9,220 | 6,823 | 284.6% |
| Investments and Other Assets | 12,614 | 14,101 | 1,487 | 11.8% |
| Total Assets | 64,239 | 74,298 | 10,059 | 15.7% |
| Liabilities | | | | |
| Current Liabilities | 20,192 | 20,971 | 779 | 3.9% |
| Notes and Accounts Payable - Trade | 5,713 | 5,351 | ▲ 362 | -6.3% |
| Other | 14,479 | 15,620 | 1,141 | 7.9% |
| Non-current Liabilities | 11,365 | 17,576 | 6,211 | 54.7% |
| Total Liabilities | 31,557 | 38,548 | 6,991 | 22.2% |
| Net Assets | | | | |
| Share capital | 32,246 | 33,677 | 1,431 | 4.4% |
| Capital Stock | 3,799 | 3,799 | 0 | 0.0% |
| Capital Surplus | 4,409 | 4,409 | 0 | 0.0% |
| Retained Earnings | 24,628 | 26,048 | 1,420 | 5.8% |
| Treasury Shares | ▲ 590 | ▲ 579 | 11 | - |
| Accumulated Other Comprehensive Income | 432 | 2,069 | 1,637 | 378.9% |
| Total Net Assets | 32,681 | 35,750 | 3,068 | 9.4% |
| Total Liabilities and Net Assets | 64,239 | 74,298 | 10,059 | 15.7% |

Decrease due to Toyama Plant Capex

Increase due to Toyama Plant Capex and product acquisition

Increase in short-term debt due to product acquisition

Increase in long-term debt due to product acquisition



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The balance sheet as of March 31 is as shown in the materials.

On the asset side, cash and deposits decreased and fixed assets increased due to Toyama plant Capex and payment of consideration for acquisition projects. On the liability side, borrowings have increased for the same reason.

As a result, total assets increased and the equity ratio declined, but we do not consider this to be at a level that raises concerns about financial stability.

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FY9/22 2Q Summary of Consolidated Statements of Cash Flows

| (¥million) | FY9/21 | FY9/22 | YoY Change | |
|---|------------|------------|------------|---------|
| | First half | First half | Amount | Ratio |
| Cash Flows from Operating Activities | 4,405 | ▲ 1,076 | ▲ 5,481 | -124.4% |
| (Major Breakdown) | | | | |
| Profit Before Income Taxes | 2,871 | 2,865 | ▲ 6 | -0.2% |
| Depreciation | 978 | 1,100 | 122 | 12.5% |
| Amortization of Goodwill | 138 | 138 | 0 | 0.0% |
| Decrease (increase) in trade receivables | ▲ 425 | ▲ 441 | ▲ 16 | 3.8% |
| Decrease (Increase) in Inventories | ▲ 42 | ▲ 1,270 | ▲ 1,228 | 2923.8% |
| Increase (decrease) in trade payables | 1,637 | ▲ 422 | ▲ 2,059 | -125.8% |
| Income Taxes Paid | ▲ 387 | ▲ 739 | ▲ 352 | 91.0% |
| Cash Flows from Investing Activities | ▲ 2,018 | ▲ 10,296 | ▲ 8,278 | 410.2% |
| (Major Breakdown) | | | | |
| Proceeds from sales of Investment Securities | 193 | - | - | - |
| Purchase of Property, Plant and Equipment | ▲ 1,800 | ▲ 2,977 | ▲ 1,177 | 65.4% |
| Purchase of Intangible Assets | ▲ 102 | ▲ 7,092 | ▲ 6,990 | 6852.9% |
| Cash Flows from Financing Activities | ▲ 3,653 | 6,988 | 10,641 | - |
| (Major Breakdown) | | | | |
| Purchase of Treasury Shares | ▲ 9,405 | - | - | - |
| Net increase (decrease) in Short-Term Loans Payable | 6,300 | 1,300 | ▲ 5,000 | -79.4% |
| Proceeds from Long-Term Loans Payable | 1,000 | 7,300 | 6,300 | 630.0% |
| Repayments of Long-Term Loans Payable | ▲ 836 | ▲ 920 | ▲ 84 | 10.0% |
| Dividends paid | ▲ 467 | ▲ 364 | 103 | -22.1% |
| Repayments of Lease Obligations | ▲ 243 | ▲ 326 | ▲ 83 | 34.2% |
| Cash and Cash Equivalents at Beginning of Period | 12,041 | 10,199 | ▲ 1,842 | -15.3% |
| Cash and Cash Equivalents at End of Period | 10,835 | 5,975 | ▲ 4,860 | -44.9% |
| Free Cash Flows | 3,154 | ▲ 11,372 | ▲ 14,526 | -460.6% |

Increase due to Toyama Plant Capex

Increase due to product acquisition



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For the same reason for cash flow, cash flows from investing activities increased and was supplemented by cash flows from financing activities.

Cash flows from operating activities was negative, but this was mainly due to a change in the supplier of bulk contrast media. The inventory that was borne by the intermediary supplier was switched to our inventory.

The large change in trade payables was due to a temporary decrease in the balance of trade payables in the previous two fiscal years. This does not mean that the purchase site was specifically reviewed in the current fiscal year.

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FY9/22 Consolidated Forecast

- Net sales : Expected to be in line with forecast, as new products, product acquisition, and existing women's healthcare products as a whole trended in line
- Operating profit : Expected to be in line with forecast, as R&D expenses are delayed to the second half

| (¥million) | FY9/21 Actual | FY9/21 Actual | FY9/22 Forecast | YoY Change (New accounting standards) | | FY9/22 First half actual | FY9/22 Second half forecast |
|---|-----------------------------|-----------------------------|-----------------------------|--|--------|--------------------------------|-----------------------------------|
| | Old accounting standards | New accounting standards | New accounting standards | Amount | Ratio | New accounting standards | New accounting standards |
| Net Sales | 33,990 | 32,645 | 35,966 | 3,321 | 10.2% | 17,726 | 18,240 |
| Operating Profit | 3,349 | 3,349 | 3,490 | 141 | 4.2% | 2,712 | 778 |
| Operating Margin | 9.9% | 10.3% | 9.7% | - | - | 15.3% | 4.3% |
| Ordinary Profit | 3,250 | 3,250 | 3,540 | 290 | 8.9% | 2,866 | 674 |
| Ordinary Margin | 9.6% | 10.0% | 9.8% | - | - | 16.2% | 3.7% |
| Profit Attributable to Owners of Parent | 2,432 | 2,432 | 2,562 | 130 | 5.3% | 1,834 | 728 |
| Profit Margin | 7.2% | 7.4% | 7.1% | - | - | 10.3% | 4.0% |
| EBITDAR ^{*1} | 7,688 | 7,688 | 8,059 | 371 | 4.8% | | |
| EBITDA ^{*2} | 5,242 | 5,242 | 5,250 | 8 | 0.2% | | |
| Capital Expenditure | 3,392 | 3,392 | 7,172 | 3,780 | 111.4% | 3,449 | 3,723 |
| Depreciation (Including Leased Equipment) | 1,893 | 1,893 | 1,760 | ▲ 133 | -7.0% | 1,109 | 651 |
| R&D Expenses | 2,446 | 2,446 | 2,809 | 363 | 14.8% | 1,152 | 1,657 |
| R&D Expenses Ratio | 7.2% | 7.5% | 7.8% | - | - | 6.5% | 9.1% |

* 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)

※ The forecast for the second half of the period of 22/9 is based on the forecast for the period of 22/9 minus the results for the first half of the period of 22/9.

※ From the beginning of FY9/22, to apply "The Accounting Standards for Recognizing Revenues" (corporate accounting standard No. 29), the above-mentioned consolidated forecast is the amount after the application of new accounting standards.

And YoY change (amount and ratio) is calculated on the assumption that new accounting standards were applied in FY9/21.



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This is the forecast for the full year.

Although profits, especially in the first half of the year, significantly exceeded our forecast, we expect the full year to be generally in line with our forecast, mainly due to the postponement of R&D expenses to a later date.

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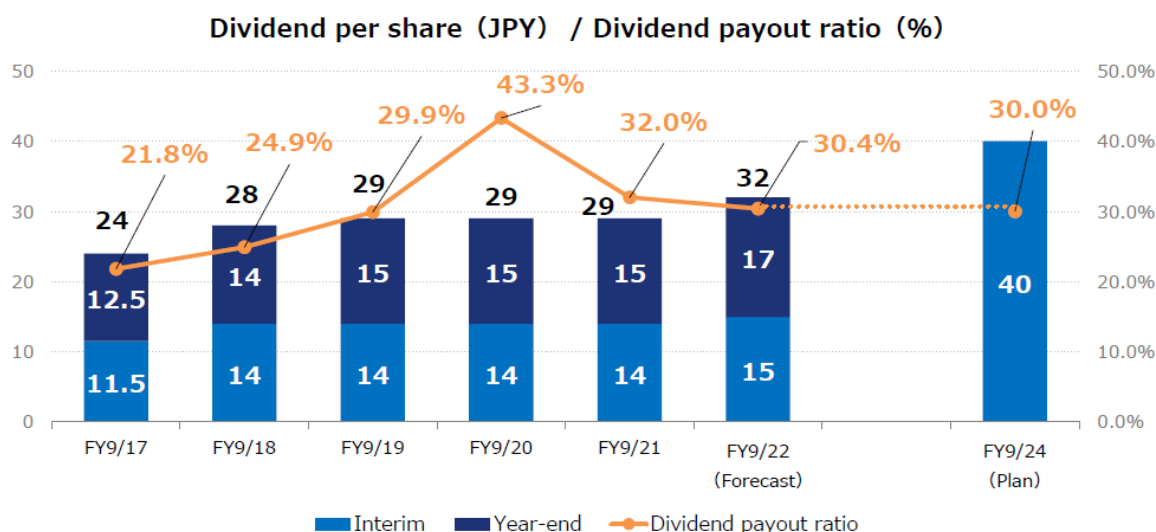
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FY9/22 Shareholder Return

- Our dividend policy is to achieve a dividend payout ratio of 30% with stable dividends. Therefore, we plan to pay 32 yen annual dividend by applying dividend payout ratio of 30% to FY9/22 forecast profit (Interim 15 yen, Year-end 17 yen)
- Announced that the interim dividend will be 15 yen per share as planned



※ On July 1, 2018, 1 common stock was split into 2 stock. Dividend per share assumes current total outstanding shares.
 ※ FY9/22 (Forecast) payout ratio is estimate at the beginning of fiscal year.



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Finally, I would like to discuss shareholder returns for the fiscal year ending September 30, 2022.

We have explained in the Corporate Report and other documents that our dividend policy is based on stable dividends, aiming for a dividend payout ratio of 30%. If profits for the current fiscal year reach the forecast level, we plan to pay 32 yen annual dividend by applying a dividend payout ratio of 30%.

Based on the first half results, we have already announced that the interim dividend will be 15 yen per share as planned.

This concludes my presentation.

Iwai: I would now like to talk about progress in Mid-term Business Plan.

I have not explained much about the business areas we are engaged in, so I would like to take some time today to talk a little about our Company's unique characteristics. What is the environment in the business areas in which we intend to invest more management resources, and in what direction do we intend to move within this environment? How are these two points aligned within Mid-term Business Plan? I would like to talk about this today.

After that, we would like to explain in detail about two important areas in which we will invest more management resources in the future. Mr. Morita will talk about investment in women's healthcare, and Mr. Mitsuhashi will talk about biosimilars.

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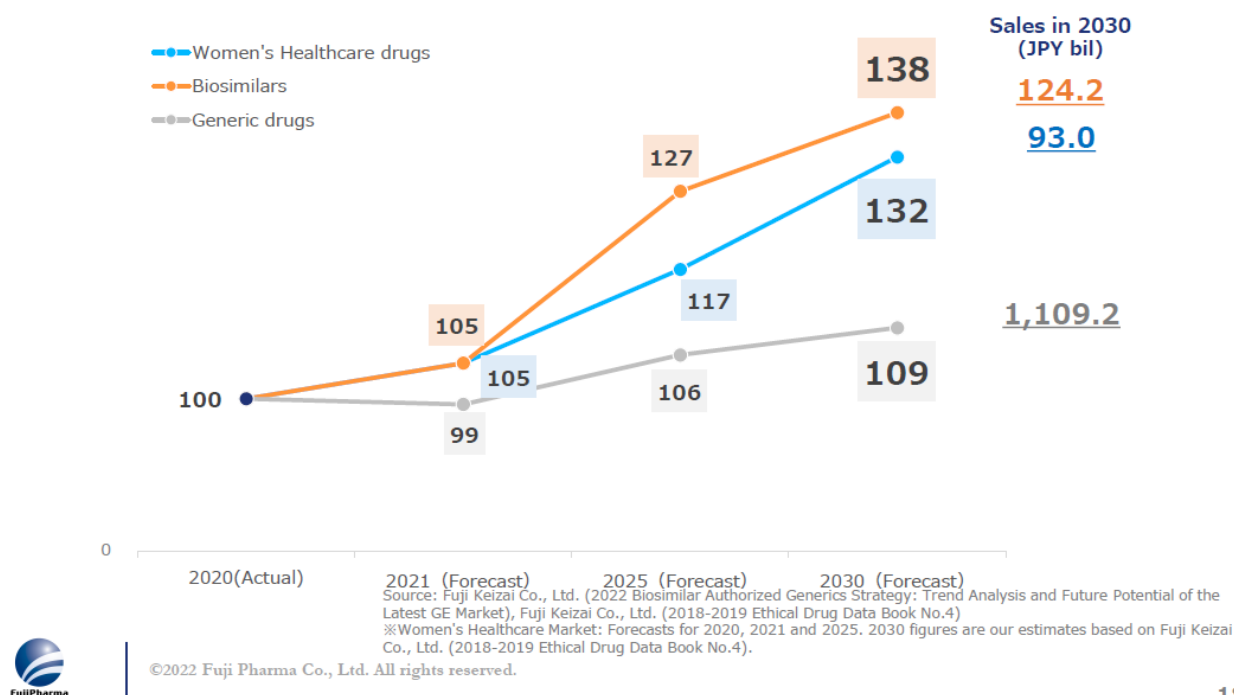
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Overview : Fuji Pharma as a Specialty Pharma (Business Domain)

- The market share of generic drugs in Japan reached almost 80% (governmental target)
- While the generic drugs market is expected to be flat, biosimilars and the Women's Healthcare drugs markets are expected to grow

➤ Domestic Women's Healthcare drugs, Biosimilars, and Generic drugs Market Forecast (2020=100)



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First, a few words about our business areas. Although we are often referred to as one of the four generic listed companies, we are making the transition from a generic pharmaceutical company to a specialty pharmaceutical company. We hope that everyone will appreciate this point today.

First, our business areas.

The generic market is represented here by a gray line graph. As you know, we have already almost reached our target of 80% of the domestic generic share in terms of volume. The generic market itself is not expected to expand significantly in the future. Therefore, the question is how to increase market share in the limited generic market.

We do not intend to compete head-to-head in the generic drug market but rather to invest further management resources in markets that will expand in the future. This is our current thinking.

Two of these are women's healthcare and biosimilars.

As shown by the orange and blue line graphs, the markets for women's healthcare and biosimilars are each expected to expand by more than 30% over the next 10 years. By further concentrating management resources in these two areas, we will further develop as a specialty pharmaceutical company and change our business format. This is our strategy.

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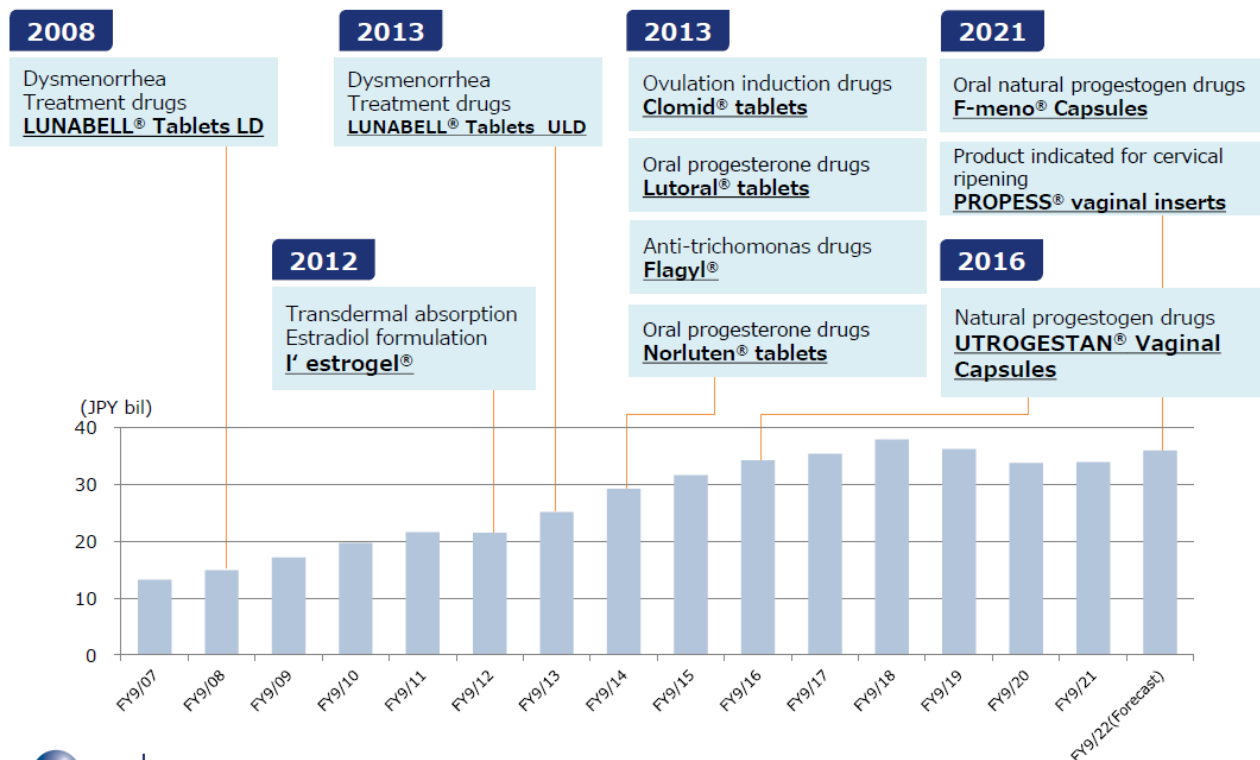
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Overview : Road to Specialty Pharma

➤ Our net sales trends and Women's Healthcare new drug line-up



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I would like to explain this point in more detail on the next slide.

This is the trajectory of our transformation into a specialty pharmaceutical company in the field of women's healthcare.

To give you a little background, our partnership began in 2008 with the marketing of LUNABELL® Tablets LD, dysmenorrhea treatment drugs. This was followed by the introduction of I' estrogel®, a transdermal estradiol brand drug, in 2012. In 2013, we acquired four women's healthcare products, mainly infertility treatment drugs, from Shionogi.

In 2016, we launched our first compound developed in-house, UTROGESTAN® Vaginal Capsules. As I have reported several times, in September last year, we received approval for F-meno® Capsules, also developed in-house, and launched them on the market.

In addition, we have been steadily expanding our new drug portfolio in the field of women's healthcare through our partnership with Ferring Pharmaceuticals in December last year.

We have built up a broad product portfolio in the women's healthcare area by combining these products with generic drugs developed by us.

In the area of women's healthcare, which we will discuss in detail later, we deal with a wide range of diseases specific to women at all life stages. We aim to work hard to develop the Fuji brand in women's healthcare. This is our strategy.

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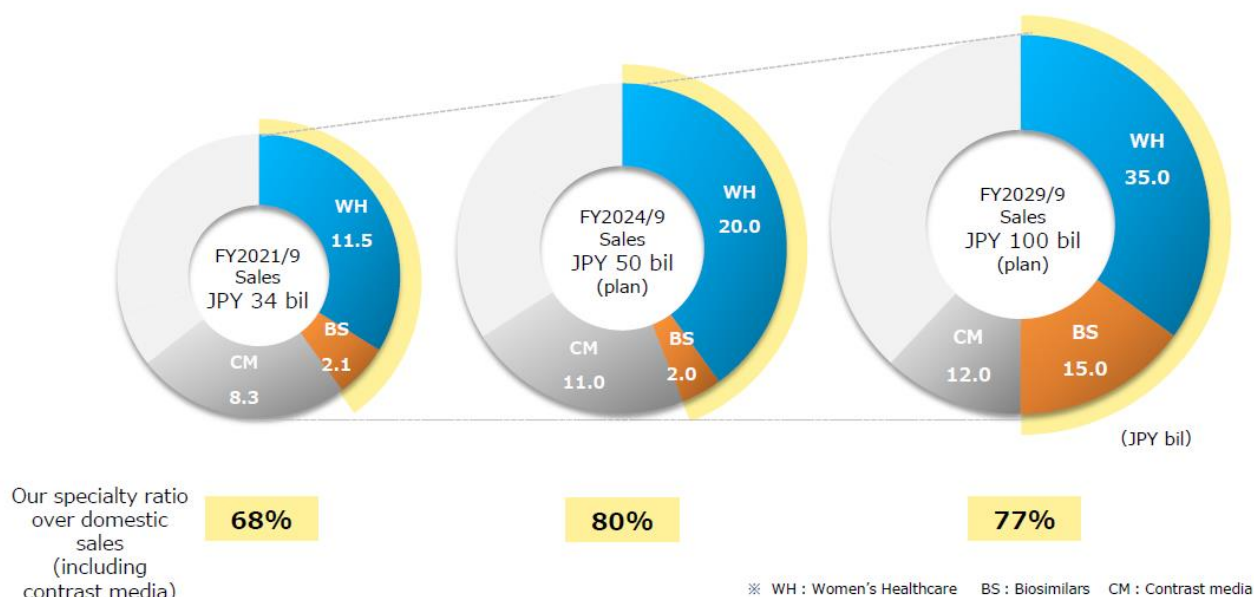
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Overview : Fuji Pharma as a Specialty Pharma

- Aggressively allocating management resources to the growing market
→ Women's Healthcare and Biosimilars gain more share in sales



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I would like to show you some concrete figures relating to what I have just mentioned.

We have shown this pie chart several times before. As I mentioned in the previous slide, by firmly building our brand in the women's healthcare area, we aim to roughly double our current sales of JPY11.5 billion to JPY20 billion by the final year of Mid-term Business Plan. By 2029, we aim to increase sales to JPY35 billion. This is the current plan.

The percentage figures are shown at the bottom of the page. This chart shows the ratio of specialty products, including contrast media, to our domestic sales.

By promoting the measures I just mentioned, we plan to raise the specialty ratio from the current 68% to 80% by September 2024, the final year of Mid-term Business Plan.

In addition, we are currently preparing for the approval of biosimilars in Japan through our partnership with Alvotech in Iceland. For the fiscal year ending March 31, 2029, we currently expect biosimilar sales of approximately JPY15 billion.

In the area of generic drug development, we will continue to develop distinctive generic drugs as we have done to date. We will strengthen our presence in women's healthcare and biosimilars by further investing management resources in these areas.

This is our strategy as we position ourselves as a specialty pharmaceutical company.

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Overview :Mid-term Business Plan (Announced in May 2020)



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With this in mind, I would now like to take another look at Mid-term Business Plan and talk about the four growth scenarios we have envisioned.

I have covered two of those. One is “No.1 in Women’s Healthcare”. The second is “Establish Biosimilar business”. By pushing ahead with these two initiatives, we will further solidify our business model as a specialty pharmaceutical company and achieve the goals of our Mid-term Business Plan.

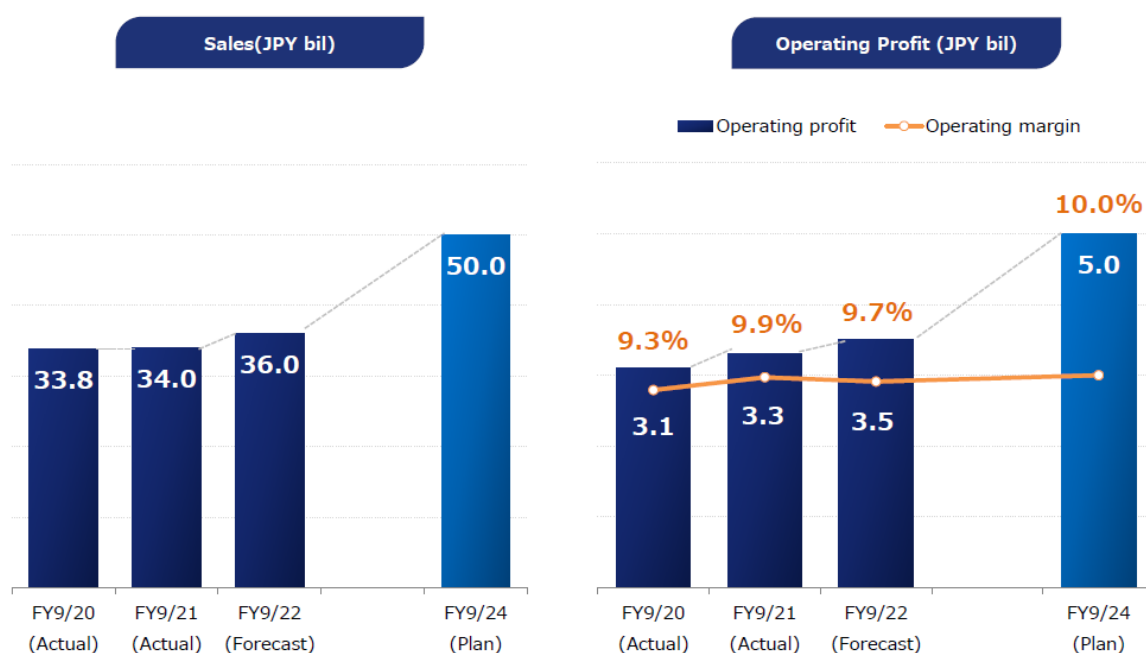
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Overview : Key Financial Targets (Announced in May 2020)



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The next slide shows the quantitative targets of Mid-term Business Plan.

By solidly implementing the strategies I just mentioned, in the fiscal year ending September 30, 2024, the final year of our Mid-term Business Plan, we aim to achieve net sales of JPY50 billion and operating profit of JPY5 billion, or 10% of our total net sales. We will strive to achieve this.

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Overview : Progress Topics for the first half of FY9/2022

| | Women's Healthcare | Contrast Media | Biosimilars | Overseas |
|--|--------------------|----------------|-------------|----------|
| Launched F-meno® capsules | ✓ | | | |
| Sales started PROPESS® | ✓ | | | |
| Developing FSN-013 (Japan, ASEAN) | ✓ | | | ✓ |
| NHI drug price listing and additional indication for insurance coverage of infertility treatment | ✓ | | | |
| Product acquisition: 4 products from Nihon Pharma | ✓ | | ✓ | |
| Additional BS contract | | | ✓ | |
| Toyama Plant capex progress | ✓ | | ✓ | ✓ |
| Materiality identification | ✓ | ✓ | ✓ | ✓ |



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I would now like to explain the priority measures we implemented in the first half of the fiscal year ending September 30, 2022 to achieve our Mid-term Business Plan.

Let me explain a little from the top. The second on the list is a new drug developed in-house. We have the launch of F-meno® Capsules. We also have the business and sales partnership with Ferring Pharmaceutical.

We will also begin Phase III clinical trials for FSN-013, a new drug that we are developing as a post-Lunabell drug. It has an August start date. We also have the response to the NHI drug price listing in conjunction with infertility treatment insurance coverage. We were also able to steadily and concretely implement milestones to achieve our Mid-term Business Plan, such as product acquisition from Nihon Pharmaceutical. These are our achievements in the first half of the year.

In addition, we have already begun construction and introduction of manufacturing facilities to ensure stable supply in the women's healthcare and biosimilar areas. I would like to explain this on the next slide.

I would now like to give a summary of our manufacturing facilities, including investment progress at the Toyama Plant, and our materiality.








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Overview : Capex on Toyama Plant

| | 2019 | 2020 | 2021 | 2022 | 2023 |
|---|------------------------|--|---|--|--|
| New tablet building WH <ul style="list-style-type: none"> Hormone tablet manufacturing / expand testing capacity High containment technology for hormone tablet manufacturing Response to PIC/S GMP inspection standards JPY 3.9 bil * | | Ground Breaking (Dec.) |  | PV (Nov.)  | |
| Adding ampoule/vial line <ul style="list-style-type: none"> Expand injection manufacturing capacity High containment technology for high pharmaceutical active injection formulation Response to PIC/S GMP inspection standards JPY 2.4 bil * | Ground Breaking |  | PQ (Mar.)  | | |
| High Potent Multi-Syringe Line BS <ul style="list-style-type: none"> Compatible with various syringe formulations and new products Expanding CMO business and exports to Europe and US Strengthen injection formulation technological Capabilities of Injection Formulations JPY 4.0 bil * | | | | Ground Breaking (Jul.) | PV (Oct.)  |
| New packaging / warehouse building <ul style="list-style-type: none"> Expand injection packaging capacity Expand product storage capacity Improve manufacturing workability JPY 2.0 bil * | |  new packaging building | Ground Breaking (Jun.)  new warehouse building | Completion New packaging building (Mar.) New warehouse building (Apr.) | |



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* Total capital expenditures (Forecast)

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First, here is the status of capex on Toyama Plant.

The first, shown in the upper left-hand corner, is the construction of a new tablet building. This is a manufacturing facility for hormone drugs, manufacturing products in the field of women's healthcare. We are currently seeking to expand in this field.

The current manufacturing capacity for hormone drugs is approximately 150 million tablets. When completed, this facility will triple our manufacturing capacity to 450 million tablets.

We have also started to introduce a multi-syringe line for biosimilars in Toyama Plant with a view to obtaining approval.

Both of these areas are priority areas for us. We will ensure a stable supply system. This is our objective.

We will provide regular updates on the progress of these investments.

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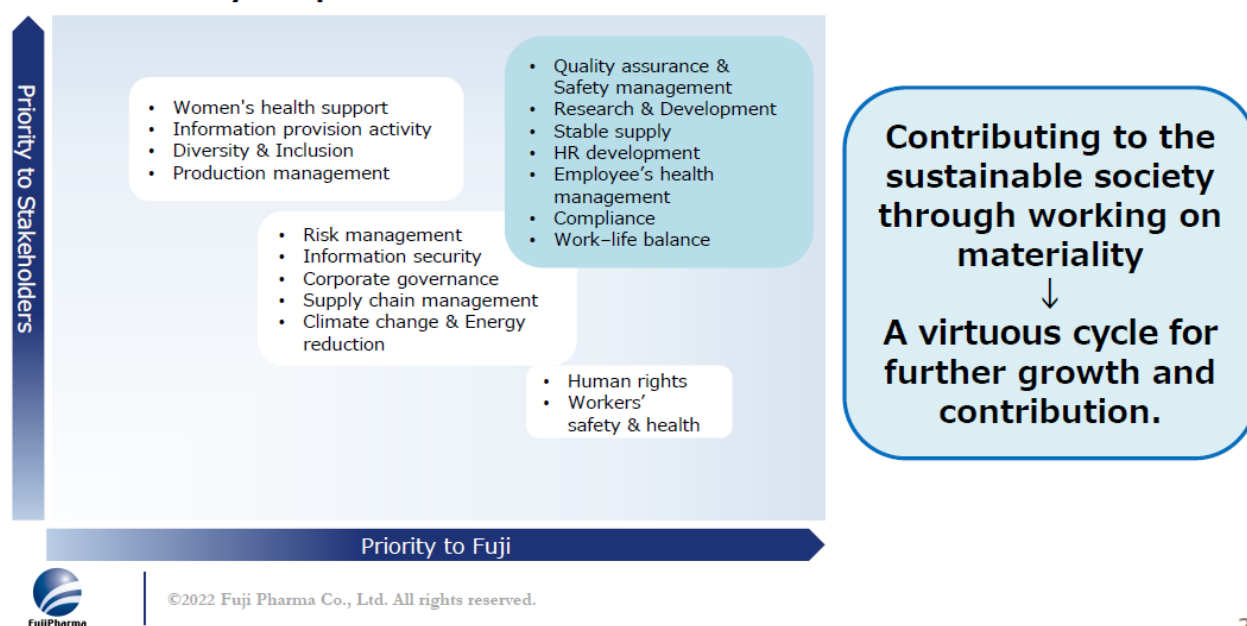


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Overview : Materiality (Identification, mapping, and priority)

- As a starting point for sustainability strategy of Mid-Term Business Plan, defined 18 materiality at sustainability committee.
- Prioritized 18 materiality thorough stakeholder surveys and company's executive interview.

● Materiality・Map



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The next step is to identify materiality. This is a reiteration of the key issues we face as we put our management philosophy into practice.

First, during the formulation of Mid-term Business Plan, we identified 18 materialities. The level of importance to us was discussed by the Sustainability Committee which is composed mainly of executive officers. The level of importance to our stakeholders was determined by surveying our business partners and shareholders.




The level of materiality will be periodically reviewed as necessary as we move forward with our materiality efforts to realize our 2030 Vision and Mid-term Business Plan.

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Overview : Selected Actions on Materiality

| Environment | Human Resource |
|--|---|
| <p>➤ ISO14001 certificate</p>  | <p>➤ ISO45001 certificate</p>  |
| | <p>➤ Selected as a Health and Productivity Management Organization</p>  <p>➤ Promoting women's empowerment (As of Apr 2022)</p> <ul style="list-style-type: none"> Number of female director and female manager ratio <ul style="list-style-type: none"> Female director : 2 Female manager ratio : 20.6% (30%※) Childcare leave ratio (as of September 2021) <ul style="list-style-type: none"> Female : 85.7% (100%※) Male : 52.6% (Over30%※) <p style="text-align: right;">※Sep 2024 Target</p> |
| Social Activity | |
| <p>➤ Special Award of NIPPON Women's Conference ®2022</p> <p>➤ Chairman's Award of The Japan Family Planning Association</p> | <p>➤ Sponsorship of women's health seminar & events</p> <ul style="list-style-type: none"> "Women's Health Week in 2022 Marunouchi Career Academy Special Seminar" (Sponsored by Nihon Keizai Shimbun, Inc.) "Our health, start talking about mental and physical Health" (Sponsored by Women's Health Action and CINRA, Inc.) |



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This is the last slide of the summary. The main initiatives related to materiality for the first half of the fiscal year ending September 30, 2022 are as presented.

In the first half of the year, we have been engaged in a wide range of activities, such as obtaining ISO and two standard approvals for the Toyama Plant. We have also obtained certification as an excellent health management corporation, reformed work styles, with a focus on promoting the role of women in the workplace, and educational activities to improve the well-being of women.

This concludes my summary.

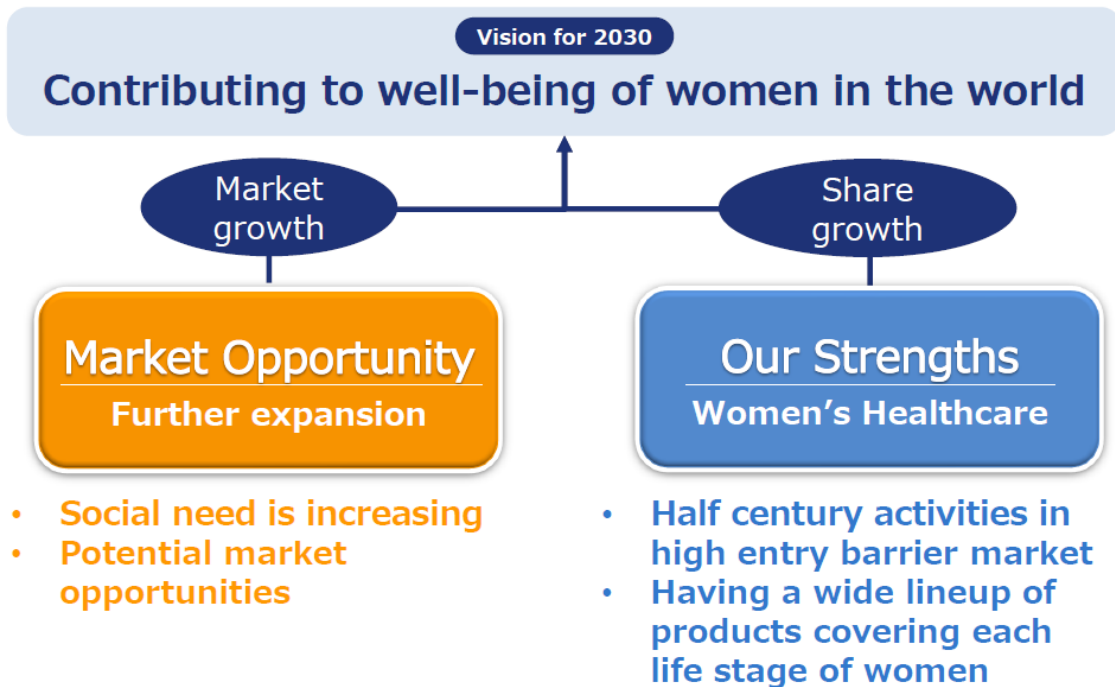
Mr. Morita will now discuss the area of women's healthcare.

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Morita: My name is Morita, and I am the director responsible for the women's healthcare area of Mid-term Business Plan. I would like to explain our efforts in the area of women's healthcare.

We have been involved in women's healthcare since its founding about half a century ago. We have focused on female hormone drugs and have grown, thanks to the support of medical professionals.

With a strong desire to make even greater contributions in the field of women's healthcare in the future, we have set our vision for 2030 as contributing to the improvement of women's well-being around the world.

In order to achieve this vision, we will focus more and more on the field of women's healthcare. In this part, I will explain the marketability and potential of the women's healthcare field and our strengths in this field.

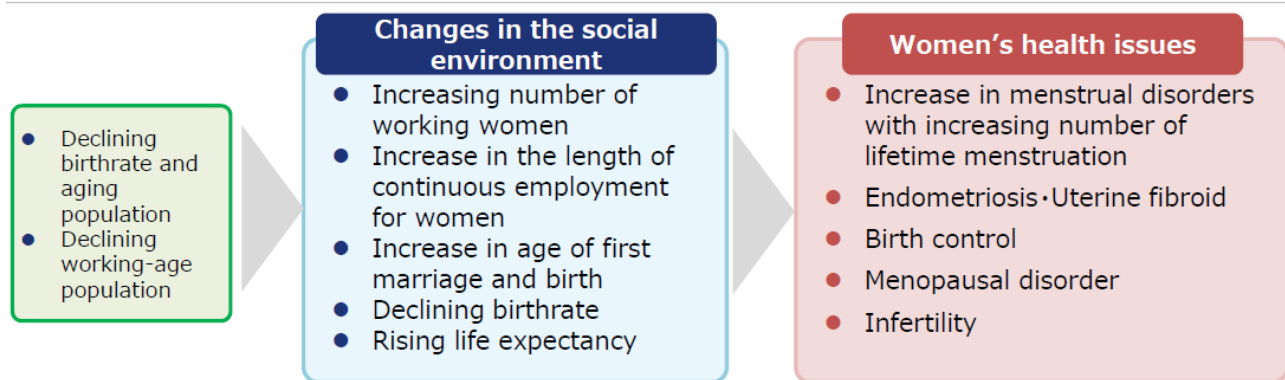
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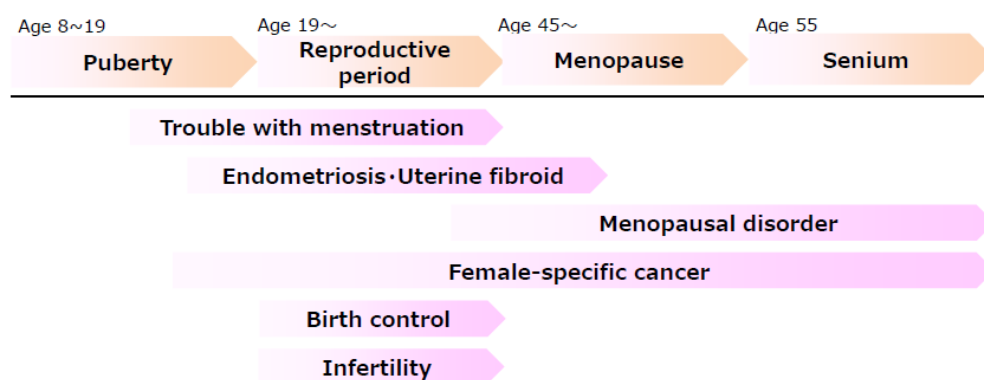
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Women's Healthcare : Contribution of Fuji to women's health issues



➤ Women's life stage and key health issues unique to women



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First, let me explain about marketability.

The declining birthrate and aging population, as well as the accompanying decline in the working-age population, are major issues facing Japan today. The social environment surrounding women has been changing dramatically, with an increase in the number of working women, increasing age of first marriage and childbearing age, and a decrease in the number of lifetime births. These changes have made the health issues faced by women more apparent than ever.

The chart below shows the major diseases and challenges for women at each stage of life.

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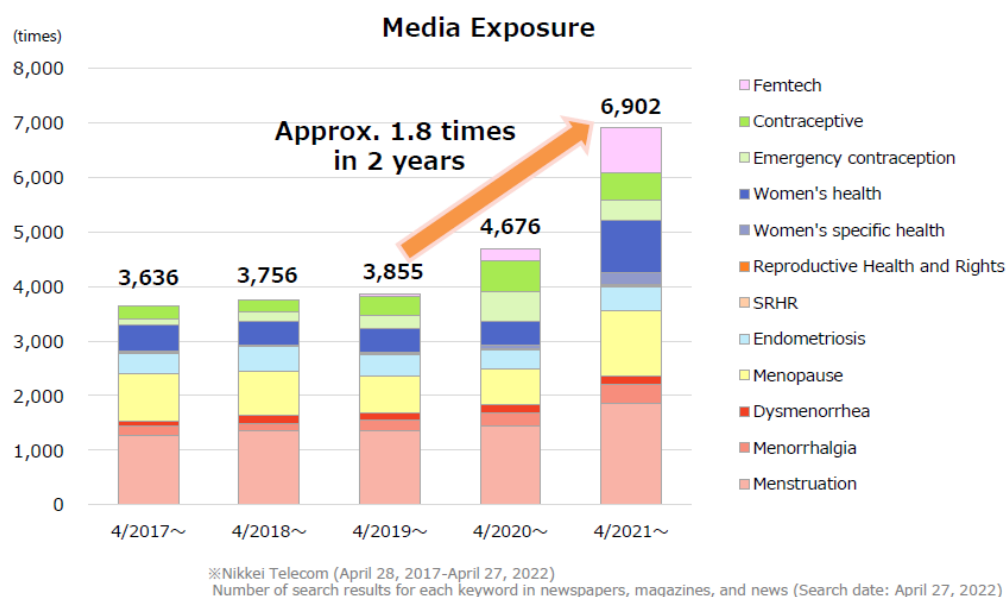
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Women's Healthcare : Women's health issues=Social issues

- ✓ In recent years, media attention to women's health issues is rising. Media exposure has been increasing approx.1.8 times in 2 years.
- ✓ Increased recognition that women's health issues is the social issue.



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Due to this type of changes in the social environment relating to women, women's health issues have been increasingly featured in the media in recent years. From 2019 to 2021, media exposure of the topic has increased by a factor of 1.8.

You may have noticed an increase in the number of news reports and programs on menstruation and menopausal disorder on TV and in newspapers in recent years. Women's health issues are currently attracting a lot of attention, and we believe that one of the main reasons for this is the lack of sufficient understanding of women's health issues in Japan until now.

However, I think you can see that changing this situation is a very important issue for improving women's well-being and, by extension, for Japanese society.

How will this increased media exposure further deepen the public's understanding of women's health issues, and how will this change the market in the area of women's healthcare in the future?

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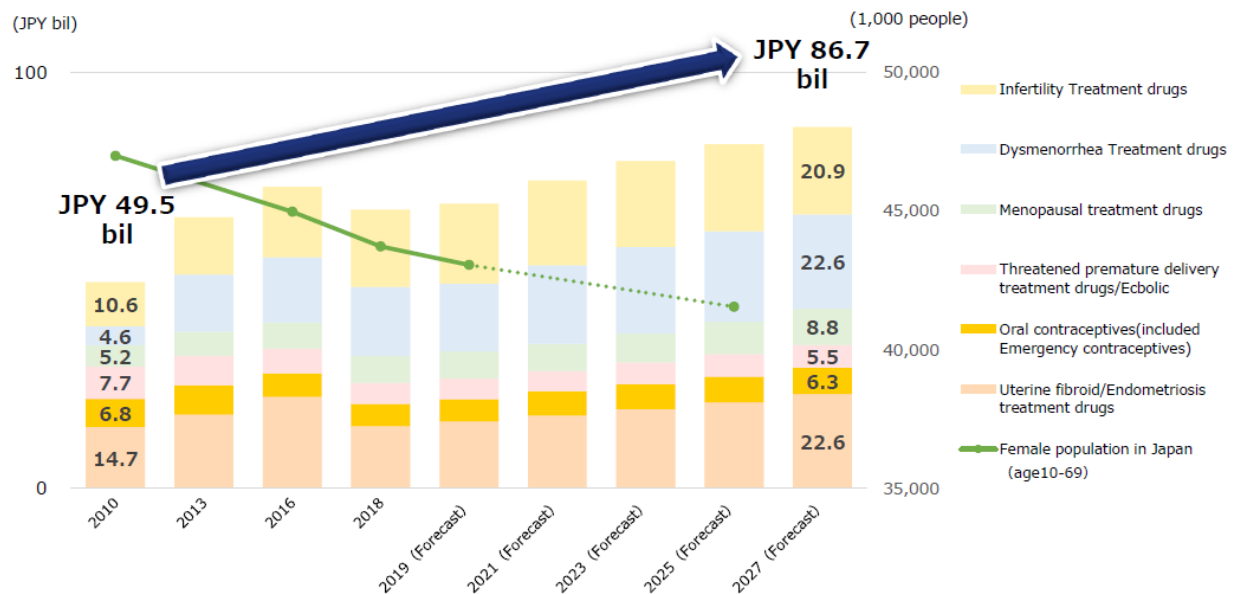
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Women's Healthcare : Domestic market

- Medication is one of the options for women's health issues.
- Gynecologic medical drug market is expanding despite population decrease.

➤ Transition of domestic gynecologic medical drug market and female population (age 10-69)



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Source: Fuji Keizai (2018-2019 Ethical Drug Data Book No. 4)
e-stat Population Dynamics Statistics 2019, National Institute of Population and Social Security Research (Population by Five-year-old Group by Region in the Future)
*The actual number of women in Japan in 2019

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Here is the domestic market forecast for women's healthcare.

The green line graph shows the female population trend in Japan from 2010 to 2019, and this forecast of the female population after 2021 is from the National Institute of Population and Social Security Research.

On the other hand, the bar graph shows the actual market for women's healthcare and a market forecast by Fuji Keizai. In Japan, the women's healthcare market is expected to grow despite the declining female population.

Why is that the case?

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Women's Healthcare : Women's life stage and key health issues

【 Puberty ~ Reproductive period 】

- Dysmenorrhea・Endometriosis
 - Dysmenorrhea Treatment drugs : 63% increase on a volume basis in the last two years ※1

【 Reproductive period 】

- Birth control
 - Oral contraceptives : Penetration rate **2.9%** (France 33.1%, USA 13.7%) ※2
 - Emergency contraceptives : Known by only **50%** of women ※3
- Pregnancy・Childbirth
 - Late childbearing : Late childbearing ratio in total number of birth (Over age 35) ※4 In 1990 few %→Year of 2010 20%→year of 2020 increasing to 30%
 - Infertility treatment : Infertility treatment covered by public health insurance from Apr 2022

【 Menopause 】

- Menopausal disorder
 - Estimated as 7 million women, more than half of the menopausal generation, having menopausal symptom.
Based on an online survey of 3,888 women of menopausal generation (40-60 years old) ※5
 - **155 thousand people** estimated to take menopausal treatment※6



※1) Source: IQVIA date JPM (September 2018 MAT, September 2020 MAT) Copyright © 2022 IQVIA. All rights reserved
※2) Source: United Nations:"Contraceptive Use by Method 2019 (from the rate of implementation of each contraceptive method in age 15 to 49 year-old marital status or equivalent reproductive age women).
※3) Source: 8th Survey Report on Life and Awareness of Males and Females in 2016 (Japan Family Planning Association)
※4) Source: Fuji pharma compiled based on the 2020 Vital Statistics Survey by the Ministry of Health, Labour and Welfare
※5) Estimated by Fuji pharma based on the Survey Results Report on Menopausal Disorder and Its Symptoms: Qlife"
※6) Estimated by Fuji pharma based on the materials published by the Ministry of Health, Labour and Welfare's Director-General for General Policy and Evaluation (in charge of statistics and information policy, and policy evaluation)

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This slide shows some of the major factors that contribute to the projected growth of the women's healthcare market.

First, the dysmenorrhea and endometriosis market, which covers the period from puberty to reproductive period, has been expanding steadily. The market has grown 63% in the last two years.

According to Japan Enlightenment Committee in Endometriosis, the number of potential dysmenorrhea patients in Japan was estimated to be about 8 million in 2012, of which only about 10% were receiving treatment at medical institutions.

Subsequently, as I mentioned earlier, although the market for dysmenorrhea is expanding, there are still a great many women who remain untreated, and the market is expected to continue to grow.

Japan is still behind the curve in terms of birth control at reproductive period. In France and the US, where the idea of women protecting their own bodies and giving birth when they want to is widespread, use of oral contraceptives is quite common. The usage rate of oral contraceptives is 33% in France and 14% in the US. In Japan, the rate is less than 3%.

Next, it is anticipated that the number of child births at an older maternal age will continue to increase and that appropriate drug treatment to support this situation will become more important. As you all know, infertility treatment will be covered by public health insurance from April of this year. Demand is expected to grow as the financial burden of treatment will be lower than before.

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As media exposure of menopause increases, there is a growing awareness that menopausal disorder is not something to be endured, but rather, something to be controlled by visiting a medical institution and receiving appropriate treatment.

Women's Healthcare : Raising awareness

● Sponsorship of various seminars on women's health

| Theme | Title | Organizer |
|--|--|--|
| To support the health and promote the active role of women, mainly in physiology | Physiological comfort project | Nikkei BP Research Institute |
| Reproductive Health & Rights | NIKKEI Round career classes | Nihon Keizai Shimbun, Inc. |
| Proper information delivery on the body of women and promotion of gynecologic visitation | 「I LADY.」 Online seminar | JOICFP, a public benefit foundation |
| Women's minds and bodies | Let's start our Healthy Mind and Physical Talks. | Women's Health Action Implementation Commission, CINRA, Inc. |



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● Utilization of health-support app "LiLuLa"



● Sponsorship in Nippon Keizai Shimbun, an article advertising on the application of infertility treatment insurance.



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I have listed a few examples, and as you can see, the field of women's healthcare is expected to continue to expand.

As shown in the slide, we have tied up with various media and organizations in order to improve the quality of life of women suffering from various health issues. We have been involved in disease awareness activities and have been working with 100 obstetricians and gynecologists to provide correct information on women's health to as many patients as possible. We are continuing our disease awareness activities through our women's health support app, LiLuLa, in order to reach as many women as possible.

From the previous explanations, we hope you understand that the women's healthcare market will continue to expand significantly in the future.

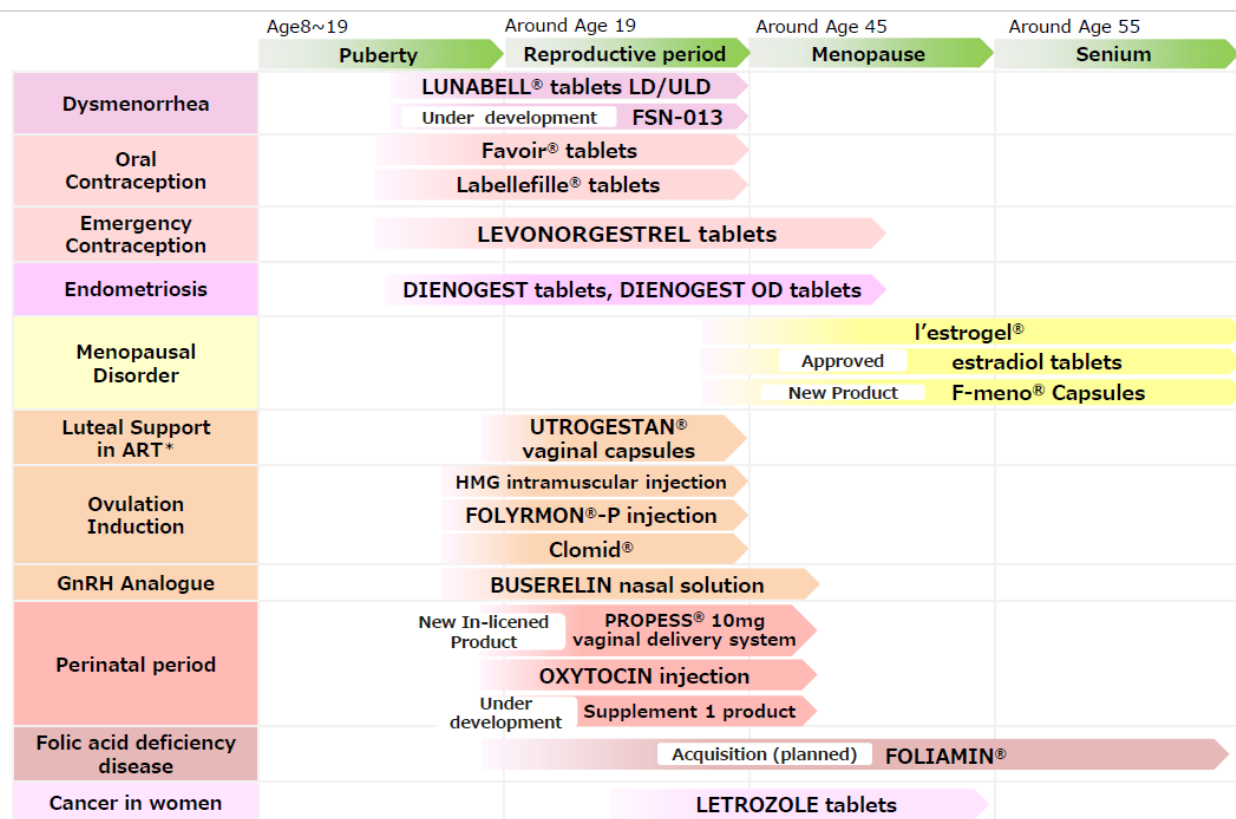
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Women's healthcare : Product Portfolio



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* ART = Assisted Reproductive Technology

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I will now explain Fuji Pharma's strengths in such an expanding market.

First, our product lineup. The horizontal axis shows the life stages of women, and the vertical axis shows typical disease areas at each life stage of women.

Listed here are our product lines. We have a broad product pipeline covering all areas.

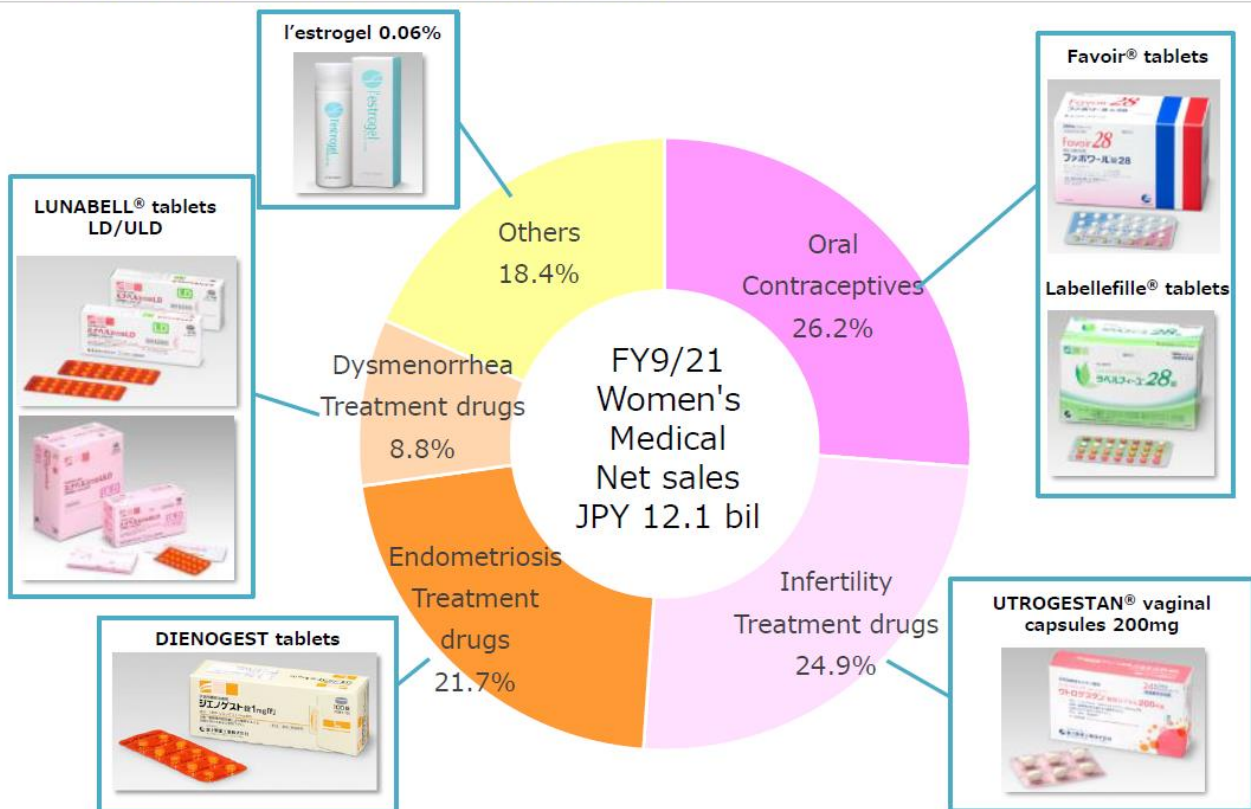
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Women's Healthcare : Sales Composition



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In addition, there is no significant gap in the composition of product sales by therapeutic area, indicating that our products cover each disease area evenly.

This gives us access to specialists in each disease area. We believe that this is a major strength of us as we continue to develop our business in the area of women's healthcare and plan to expand sales.

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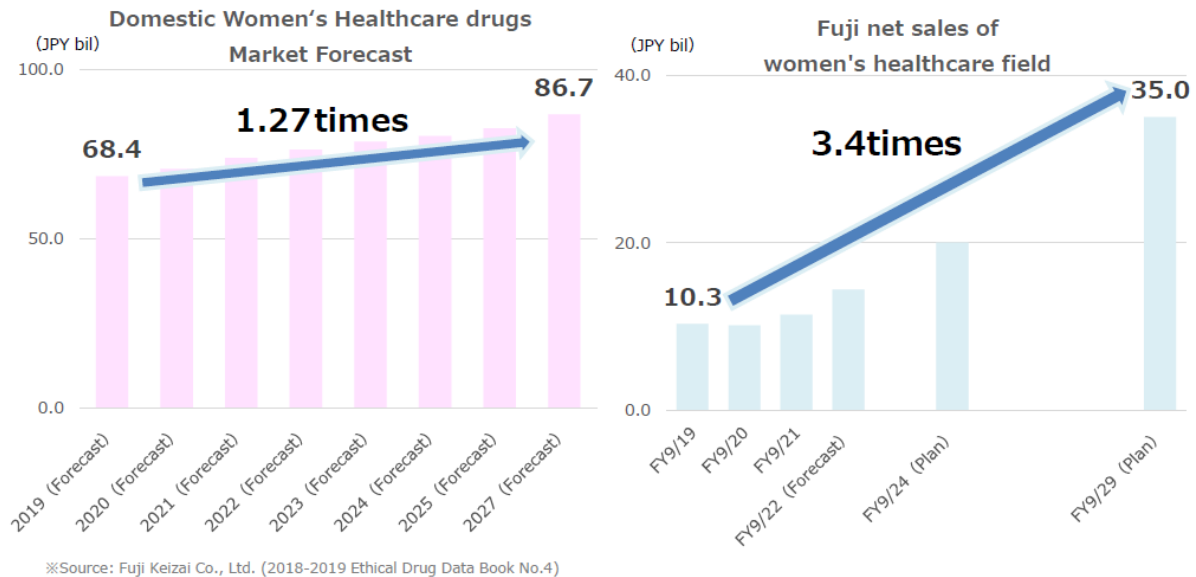
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Women's Healthcare : Sales trends and market share

- As a pioneer in hormone drugs, established a solid presence in women's healthcare.
- Our purpose is to contribute to improving well-being of women.
- While enhancing its presence as a specialty pharma company, Fuji fulfills its mission of solving health problems for women.



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I will now present our forecast sales trends and plans in the area of women's healthcare.

The figure on the left is the future forecast for the women's healthcare market that we introduced earlier. The market is projected to expand 1.27x between 2019 and 2027.

The figure on the right is our sales plan. We plan to increase our sales by a factor of 3.4 by 2029 in the expanding women's healthcare market. In other words, we plan to further expand sales and increase our market share by leveraging our strengths in the women's healthcare market, which is expected to grow in the future.

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Women's Healthcare : Fuji Pharma's contribution to issues

【 Puberty ~ Reproductive period 】

- Dysmenorrhea・Endometriosis
 - Dysmenorrhea Treatment drugs : 63% increase on a volume basis in the last two years ※

Development of “FSN-013” in Japan and ASEAN is going well

| | Japan | Tie |
|----------------------|--|--|
| Expected indications | Dysmenorrhea Pain associated with endometriosis | Contraception |
| Development progress | From August 2021 During Phase III | Applied import approval in September 2021 (accepted in November) |
| Launching period | 2024 (target) | 2023 (target) |
| | <ul style="list-style-type: none"> • Joint development and sales contract with M3, Inc. • Development: Clinical trials conducted by CRO, a M3 subsidiary →Both companies share progress and thoroughly manage schedules. • Sales: Use M3's e-promotion for F-meno® sales promotion. FSN-013 will also be supported by M3. | <ul style="list-style-type: none"> • Planning in-house sales in OLIC in Thailand. Expanding Sales&Marketing organisation • License process in Thailand proceeds as planned. • Introduced GE products for women's healthcare and preparing for import approval application to expand portfolio. • Sublicenses planned in ASEAN other than Thailand. |



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How can we make that happen? The following slides will introduce the main items.

First, in the area of dysmenorrhea and endometriosis, we are aiming to launch the new drug FSN-013.

The drug is currently in development domestically, and will be a next-generation treatment for dysmenorrhea. It is a combination of drospirenone and estetrol, a natural follicular hormone with some unique properties.

It is expected to reduce the side effects reported with the conventional combination therapy used for dysmenorrhea, which includes the follicular hormone ethinylestradiol.

Estetrol has less effect on the blood coagulation system, less effect on lipids, and is less likely to cause weight gain than existing drugs. It is a new global drug that was just approved and launched as an oral contraceptive in the US and Europe last year. We have licensed the drug in Japan and ASEAN countries, and are developing it in Japan for the indication of improving pain associated with dysmenorrhea and endometriosis. We are currently conducting Phase III clinical trials.

We will deliver a new treatment option for dysmenorrhea in the next few years. The dysmenorrhea market is one of the largest in the field of women's healthcare, and it is continuing to expand.

In Thailand, we have already filed an application for import approval as oral contraceptive and aim to launch the product in 2023.

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Women's Healthcare : Fuji Pharma's contribution to issues

【 Reproductive period 】

● Birth control

- Oral contraceptives : Penetration rate **2.9%** (France 33.1%, USA 13.7%) ※1
- Emergency contraceptives : Known by only **50%** of women ※2

Strengthen enlightenment and manufacturing capacity of oral contraceptives (Favor®, Labellefil®).

● Pregnancy・Childbirth

- Late childbearing : Late childbearing ratio in total number of birth (Over age 35) ※3 In 1990 few %→Year of 2010 20%→year of 2020 increasing to 30%

Global Standard Therapy to Japan by Acquisition of Distribution Rights of PROPESS®

- Infertility treatment : Infertility treatment covered by public health insurance from Apr 2022

Add NHI price list 1 item, add indication 8 ingredients 13 items.

Meet domestic fertility treatment demand(Approx. 2 times※4) with our products

※1) Source: United Nations: "Contraceptive Use by Method 2019 (from the rate of implementation of each contraceptive method in 15-to 49-year-old marital status or equivalent reproductive age women)."

※2) Source: "8th Survey Report on Life and Awareness of Males and Females 2016 (Japan Family Planning Association)"

※3) Source: In-house compilation based on the 2020 Population Dynamics Survey by the Ministry of Health, Labour and Welfare

※4) Source: Fuji Keizai Co., Ltd. (current status and future outlook of fertility treatment market in which insurance coverage is applied)



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In the area of birth control, in order to raise the natural right of women to be able to give birth when they want to, to the level of developed countries, we will continue to focus on raising awareness of birth control in cooperation with obstetricians and gynecologists and various organizations that focus on raising awareness.

In addition to raising awareness, in response to the future expansion of the oral contraceptive market, we will further increase its presence in this area by investing in facilities to strengthen its supply system. We are constructing a new tablet building in order to fulfill our responsibility, with one of the few manufacturing facilities responsible for the domestic production of oral contraceptives.

In the area of pregnancy and childbirth, we entered into a marketing agreement with Ferring Pharmaceutical last December for PROPESS, the product indicated for cervical ripening. This is one of the drugs that will address the challenges posed by the increasing proportion of births at an older maternal age.

Although PROPESS has long been a standard drug globally, it was made available in Japan less than two years ago. In Japan, this is the first new product in the area of childbirth in 20 years, and we will strive to promote this drug domestically.

We have a strong connection with the area of infertility treatment. The percentage of children born through in vitro fertilization was 1 in 40 in 2009, but in 2019, the figure is 1 in 14.

Furthermore, due to the expansion of public health insurance coverage, Fuji Keizai forecasts that the market will double between 2020 and 2024. It is expected to become increasingly familiar to us all. We, as a company with a top-class product lineup in this field in Japan, will make a company-wide effort to meet the growing demand.

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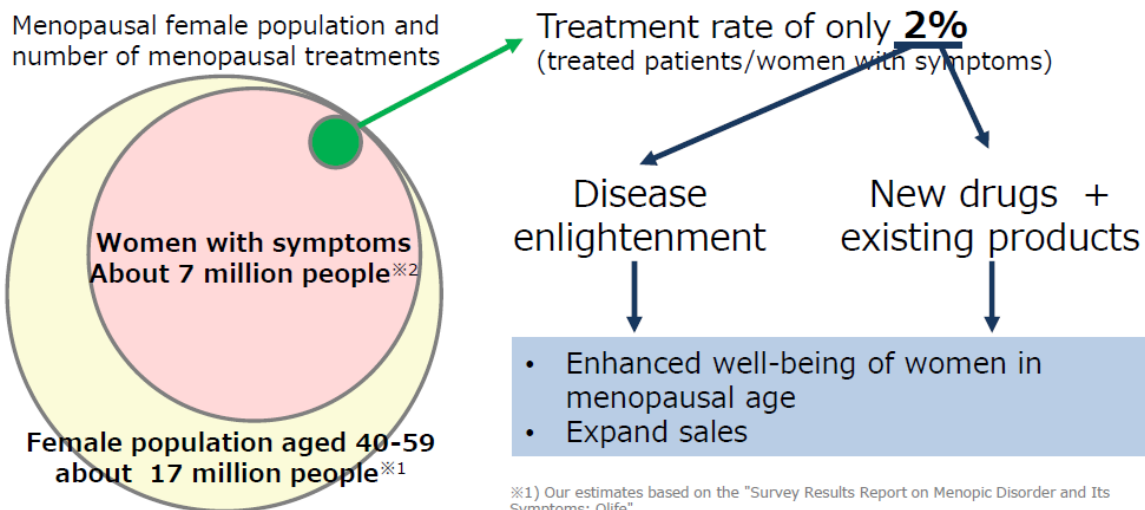
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【 Menopause 】

● Menopausal disorder

- Estimated as 7 million women, more than half of the menopausal generation, having menopausal symptom.
Based on an online survey of 3,888 women of menopausal generation (40-60 years old) ※¹
- **155 thousand people** estimated to take menopausal treatment ※²



※¹) Our estimates based on the "Survey Results Report on Menopausal Disorder and Its Symptoms: Qlife"
※²) Our estimates are based on the materials published by the Ministry of Health, Labour and Welfare's Department of Policies Control Secretary (in charge of statistics and information policy, and policy evaluation)



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Finally, the menopause disorder area.

It is estimated that about 7 million women have menopausal symptoms out of a population of about 17 million women between the ages of 40 and 59, which is considered to be the menopausal period. However, only 155,000 of these patients are actually receiving treatment. That's about 2% of all women with symptoms.

We will work with obstetricians and gynecologists and various organizations to raise awareness of the fact that menopause disorder in women is not something to be endured, and women can lead a comfortable life by receiving appropriate treatment.

In November last year, we launched F-meno capsules, the first progestogen product in Japan to be marketed for menopause-related indications. The launch of this product heralds the spread of hormone replacement therapy, or HRT, in Japan. We are focusing on information provision activities to contribute to improving the quality of life of menopausal women.

I have discussed women's health issues in Japan, the market potential for future growth, and Fuji Pharma's strengths and business plans in the area of women's healthcare.

This concludes my presentation on the women's healthcare field.

Next, Mr. Mitsuhashi will talk about biosimilars, another area on which we are focusing our efforts.

Support

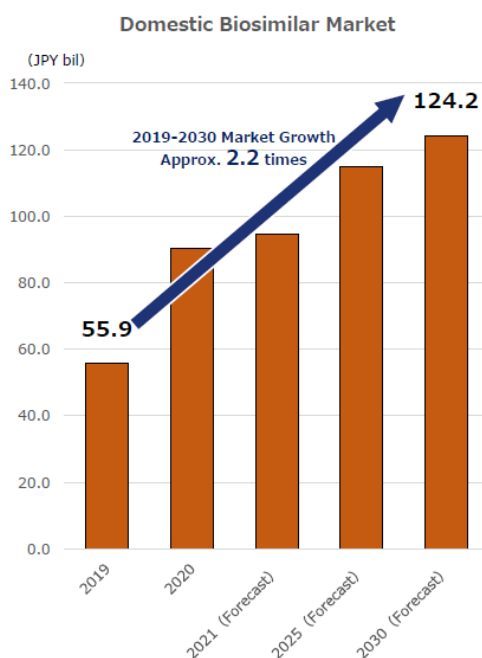
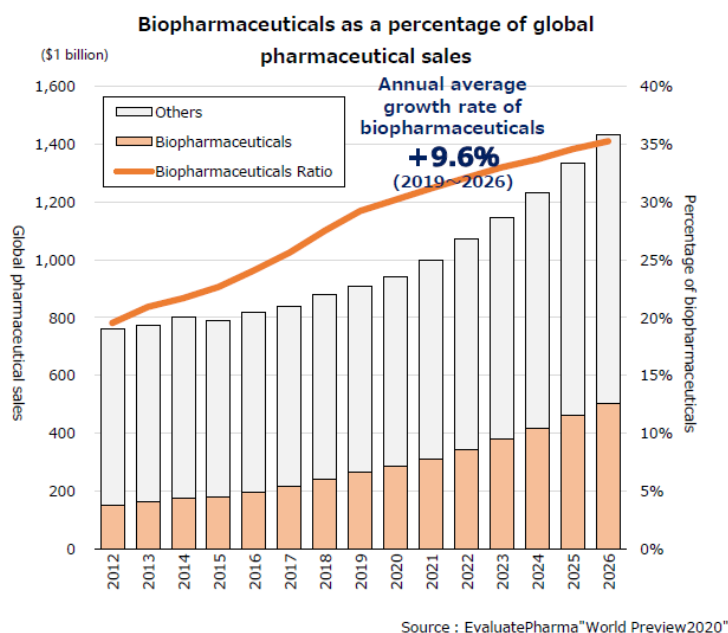
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Biosimilars : Domestic market

- Biopharmaceuticals, launched in the 1970s, faces patent expiry.
- Biosimilars are gradually replacing expensive biopharmaceuticals to reduce medical costs, and the market is expanding



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※Source: Fuji Keizai Co., Ltd., "2022 Biosimilars and Authorized Generics Strategy Latest GE Market Trend Analysis and Future Prospects"

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Mitsuhashi: Mitsuhashi here. I will now explain our biosimilars business initiatives. Thank you.

First, I would like to give an introduction to the biosimilars market.

As you are aware, the share of biopharmaceuticals in global pharmaceutical sales continues to grow significantly. This is also true of Japan. In recent years, biopharmaceuticals have been facing patent expiration one after another. There are growing expectations for biosimilars to replace expensive biopharmaceuticals, with the anticipated benefits of reducing medical costs, reducing patient burden, and supporting the universal health insurance system.

The biosimilars market is expected to grow to JPY124.2 billion by 2030. The market is expected to be 2.2x larger than in 2019.

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Biosimilars : Domestic Situation

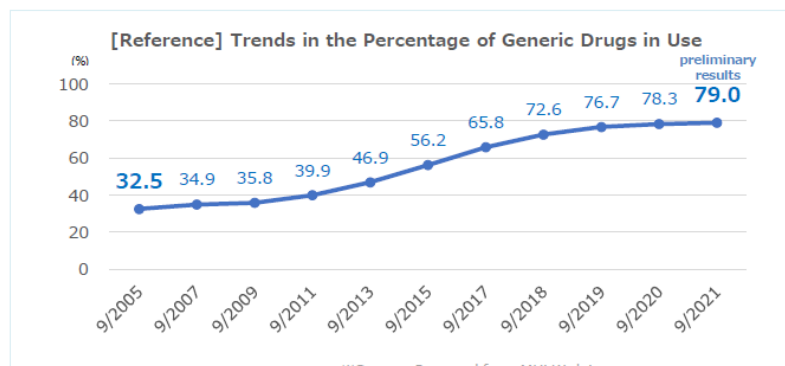
● Gradually advancing the use of biosimilars as a national medical policy

- April 2020: New incentive for introduction of biosimilars was established at the time of Revision of Medical Fee
- September 2021: Promoting the use of biosimilars was specified in the Pharmaceutical Industry Vision 2021
- April 2022: Incentive for introduction of biosimilars was expanded at the time of Revision of Medical Fee, etc.

Pharmaceutical and Food Examination
Notification No. 0304007
Guidelines for biosimilars definition,
coverage, and ensuring quality, safety
and efficacy

Revision of Medical Fee
New incentives for biosimilar
introduction

Revision of Medical Fee
Expanded range of incentives for
biosimilar introduction



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※Source: Prepared from MHLW data
(Quantity share refers to the quantity share of "generic drugs" with "Original drugs with generic drugs on the market" and "generic drugs" as the denominator.)

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This trend is also evident in national policies. The Japanese government has indicated in its Framework Policy that it intends to promote the research, development, and spread of biosimilars. Just as various measures have been taken to promote the use of generics, specific measures to promote biosimilars are also being considered and promoted.

At present, the use of biosimilars varies from a few percent to just under 90%, depending on the product. However, the overall percentage of biosimilars in use is increasing every year.

We will work to gain the understanding of medical professionals and patients regarding the quality, safety, and efficacy of biosimilars and support the spread of biosimilars.

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Biosimilars : Domestic approval status and our strategy

- Biosimilars have high entry barriers
 - High cost for domestic development (clinical trials are required)
 - Necessity of securing API to achieve stable supply
 - Manufacturing facilities and technologies for a wide variety of dosage forms of biopharmaceuticals

■ Domestic biosimilar approval status

- 16 ingredients 37 items approved (as of May 2022)
- 6 ingredients are approved for only 1 company (37.5%).

Number of approved companies per ingredient: 2.25

Number of distributors per ingredient: 2.38

■ Our strategy

● Exclusive partnership with Alvotech for development and commercialization of biosimilars in Japan (November 2018)

- Already secured a large number of development candidates
- Alvotech's excellent cost-competitive ability and API supply capabilities, with many foreign sales partners
- Collaborative development by Alvotech and Fujii
- Preparing for manufacturing both abroad and domestically (domestic = high potent multi-syringe line at the Toyama Plant)



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So far, 37 biosimilars with 16 active ingredients have been approved in Japan.

With an average of 2.25 approved companies per ingredient and 2.38 marketing companies per ingredient, the number of competing companies is small. The situation is very different from generics, where many companies are in the market. There are high barriers to entry for development, manufacturing, and stable supply. The number of manufacturers entering the market is limited.

By forming a partnership with Alvotech, which has a large number of development candidates and many overseas sales companies as partners, we have secured an abundant pipeline, reduced development costs, and gained cost competitiveness. By establishing a system that enables manufacture of a stable supply either in Japan or overseas, we will differentiate ourselves from our competitors.

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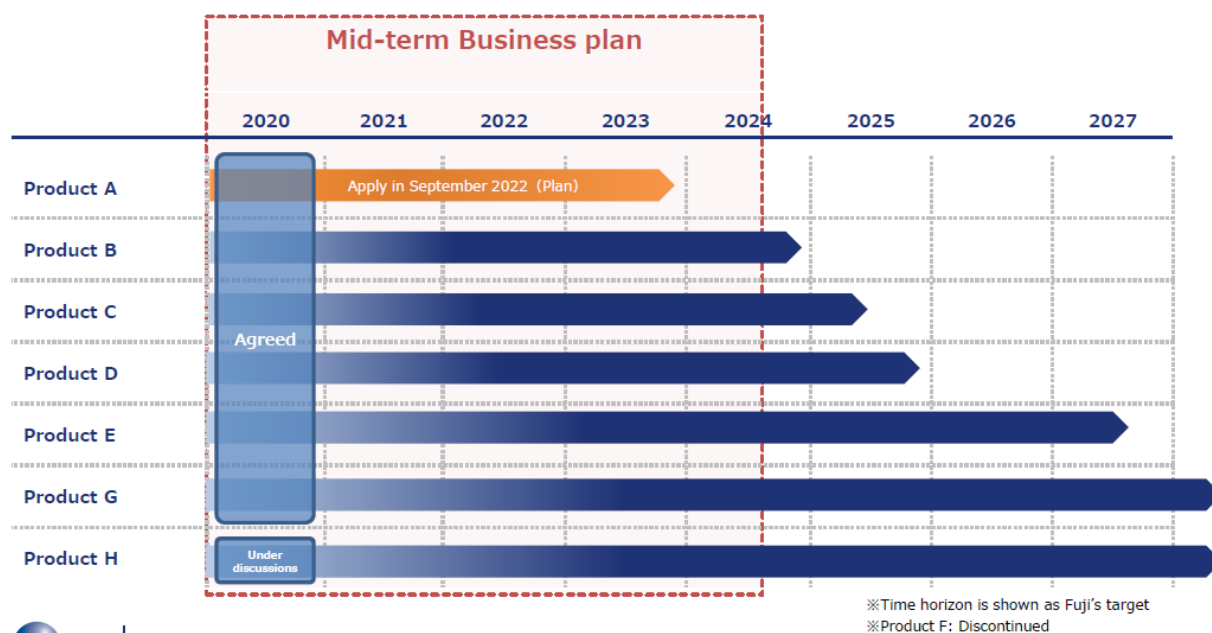
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Biosimilars : Development progress

- November 2018 : Agreed the partnership with Alvotech to commercialize biosimilars in Japan
- February 2022 : Agreed the terms with Alvotech for the development and marketing of 1 product in Japan

Fuji & Alvotech have reached agreement on the terms for total 6 products
(Domestic leading original drugs market size: approximately JPY 220 bil in total)



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Continuing on, here is the status of development.

One product was added to the development portfolio in February of this year, bringing the total to six products. We are currently in discussions with Alvotech regarding one additional product. The domestic market for the six products is currently worth approximately JPY220 billion, and it continues to grow.

Finally, in September of this year, we plan to submit an application for manufacturing and marketing approval for one product.

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Biosimilars : Acquisition of 4 products from Nihon Pharmaceutical Co., Ltd.

● Overview

- December 28, 2021 : Concluded an asset transfer agreement to acquire marketing approval for 4 products from Nihon Pharma
 - February 28, 2022 : Completion of the asset transfer related to the acquisition from Nihon Pharma
 - From March 2022 : Recording net sales of 4 products
- ※ The timing of acquisition will be discussed and decided in the future

● 4 products acquired

| | SULPREP ® | MINCLEA ® | FOLIAMIN ® | OSVAN ® |
|-------------|---|--|---|--|
| Launched | 2021 | 2011 | 1989 | 1976/1995/1998 |
| Indications | Elimination of intestinal contents in pretreatment during colonoscopy | Suppression of gastric peristalsis during upper gastrointestinal endoscopy | Prevention and treatment of folate deficiency | Disinfection of fingers, skin, surgical site, etc. |
| Dosage form | PET bottle formulation | Injection | Powders, tablets, and injection | Liquid |



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Measures with a view to marketing biosimilars are also underway.

The transfer of product sales and manufacturing and marketing approval is quite a complex matter, but it is significant in the synergies that it will bring in the future sales of biosimilars as we move forward.

This is true for the products shown here, for which we concluded an agreement with Nihon Pharmaceutical last December. We believe that this will be a positive factor in the sales of biosimilars.

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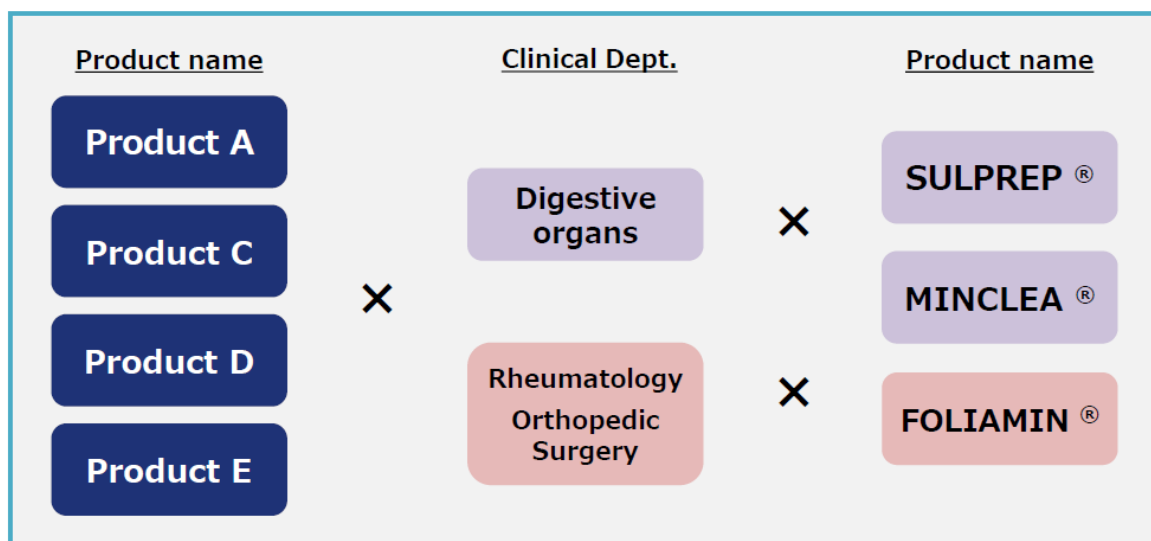
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Biosimilars : Leveraging products acquired from Nihon Pharma

● Purpose of Acquisition

- Foundation for future sales of biosimilars
- With the products acquired from Nihon Pharma, we will build relationships with medical departments to secure a foundation for marketing of biosimilar products



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In many cases, our target customers for the biosimilars that we are promoting are medical departments that we have not focused on in the past. This includes departments such as gastroenterology and rheumatology.

SULPREP and MINCLEA are used in gastroenterology. FOLIAMIN is prescribed in rheumatology. We believe that adding these products to our product portfolio is an effective way to secure a foundation for our information provision activities by building relationships with healthcare professionals.

In this way, we will continue to transfer sales and acquisition in a manner that generates synergy.

Last but not least, biopharmaceuticals have excellent therapeutic effects on many diseases. However, it has been pointed out that high drug costs lead to an economic burden on patients and an increase in social security costs.

Biosimilars not only contribute to reducing healthcare costs, but also improve access to treatment for patients who cannot bear the financial burden of biopharmaceuticals. The Japanese government is supporting this initiative.

There are few companies in the market due to high barriers to entry in development, manufacturing, and stable supply. We intend to invest resources in this area to differentiate ourselves from our competitors and prepare for sales from various angles in order to deliver necessary medical care to patients who need it.

Iwai: This is the last slide for today.

As I explained at the beginning of this presentation, performance in the fiscal year to date has been favorable. Today, we explained the characteristics of us as a specialty pharmaceutical company.

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In order to achieve the goals of Mid-term Business Plan, we will further invest management resources in the two areas of women's healthcare and biosimilars. Both of these areas are expected to grow further in the future.

As a result, we aim to achieve our goals of JPY50 billion in consolidated net sales and JPY5 billion in operating profit in the final year of Mid-term Business Plan.

With this, I would like to conclude my presentation of the second quarter and financial results for the period ending September 30, 2022.

Moderator: Thank you very much.

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Question & Answer

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

Let's take the first question.

The four products you are taking over from Nihon Pharmaceutical have sales of approximately JPY600 million. What is the sales forecast for the full year? Thank you.

Iwai [M]: Thank you very much. I will pass this question to Mr. Sato.

Sato [A]: Sato here. Thank you for your question.

Unfortunately, we are not able to disclose the full-year sales forecast for the products we took over from Nihon Pharmaceutical.

However, as an aside, the sales have been recorded since March. The figure of approximately JPY600 million, which was recorded in the first half of the fiscal year, is a one-time procedural item for the acquisition, and a portion of the amount planned for the second half of the fiscal year was shifted to the first half of the fiscal year. Therefore, you may have trouble calculating the full-year sales forecast by extrapolating out from this figure. Thank you.

Moderator [Q]: Thank you very much. Now for your next question.

You mentioned that sales of contrast media are declining due to the NHI price revision, but have sales been constant by volume? Thank you.

Iwai [A]: I would like to respond to this point.

In the area of contrast media, the decrease in sales is mostly due to the NHI price revision. There is currently no major change in sales by volume.

However, for some of our contrast media, it has become difficult to find cost-based advantages of our products compared to the prices of brand-name products. In this regard, we intend to closely monitor future sales conditions and other factors. That is all.

Moderator [Q]: Thank you very much. Now for your next question.

Sales forecasts for several of your fertility products have exceeded 50% progress toward the full-year forecast. Do you also feel that the infertility treatment market is expanding following the expansion of insurance coverage for infertility treatment? Thank you.

Iwai [M]: Thank you very much. Mr. Morita will take this question.

Morita [A]: Thank you. First of all, your question is about the sales budget progress exceeding 50%, but what is the trend of sales in the second half of the year.

Medical institutions tended to purchase some products in bulk before the NHI price revision in April of this year, and progress exceeded 50% in the first half of the year. Therefore, we expect that the impact of this

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change will be felt a little at the beginning of the second half of the fiscal year. For the entire fiscal year, we believe that performance will be favorable.

Secondly, you asked whether we have actually seen an expansion of the market after the expansion of insurance coverage for infertility treatment.

We have heard that the number of patients is increasing in some medical fields since the insurance coverage of infertility treatment has actually started. However, we believe that it will take some more time before we get a fuller picture.

We have a very large responsibility to fulfill in this area, as I mentioned earlier, in terms of the number of products in our product lineup. We will do our best to meet the demand.

Some of our fertility products cannot be manufactured flexibly in a short period of time to meet demand. However, it seems unlikely that sales will surge in the short term. That is all.

Moderator [Q]: Thank you very much. Now for your next question.

The percentage of women treated for menopause in Japan is still small. What is the prevalence of hormone replacement therapy in Japan? Thank you.

Iwai [M]: Mr. Morita will answer this question as well.

Morita [A]: This is about the prevalence of hormone replacement therapy in Japan.

Although the data is a bit old, the prevalence of HRT (hormone replacement therapy) among postmenopausal women is said to be less than 2% in Japan, compared to 30% to 40% in the US and Europe. This is by far the lowest percentage among developed countries.

As I explained earlier, we believe that this is due to the lack of knowledge and understanding of menopause and hormone replacement therapy in Japan. We are committed to changing this situation by raising awareness of the disease. That is all.

Moderator [Q]: Thank you very much. It is almost time for us to end, so we will conclude with the next question.

The dysmenorrhea market in Japan is expanding. With other companies' new drugs, generics, and authorized generics also being launched, competition seems to be getting tougher. What are the characteristics of FSN-013, your company's new drug currently under development? Thank you.

Iwai [A]: Thank you very much. As mentioned in the presentation, FSN-013 has a new ingredient called estetrol, which is a natural follicular hormone. This formulation uses estetrol, which has been reported to have a better side effect profile than existing treatments for dysmenorrhea.

We believe that by launching these new products, we will be able to offer new options in the dysmenorrhea treatment market that we have pioneered together with Nobelpharma. Thank you.

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Moderator [M]: Thank you very much. We received a lot of questions, and we apologize for not being able to answer all of them. This concludes the question-and-answer session.

If you have any other questions, please contact the Corporate Planning Department as indicated in the presentation materials.

This concludes the presentation of the financial results for Fuji Pharma for the second quarter of the fiscal year ending September 30, 2022.

Thank you for joining us.

[END]

Document Notes

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