

Presentation

Takasaki: Hello everyone. Thank you very much for attending today's financial results briefing for the second quarter of the fiscal year ending September 30, 2024, of Fuji Pharma Co., Ltd.

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

Iwai: Thank you very much.

Takasaki: This is Mr. Shuhei Morita, Director and Head of Corporate Planning.

Morita: Thank you very much.

Takasaki: My name is Takasaki, the moderator. Thank you very much for joining today.

Today, we will give you an explanation of the business environment in Fuji Pharma's focus areas, a summary of financial results for the second quarter of the fiscal year ending September 30, 2024, the consolidated financial outlook for the full fiscal year ending September 30, 2024, and the progress of products under development.

We will then proceed to the Question & Answer session. We will be happy to answer as many questions as time permits, so please do not hesitate to ask any questions you may have. You may send us questions from the chat function anytime during the presentation.

We also ask for your cooperation in filling out the questionnaire to help us in our future IR activities. The survey can be found at the bottom of the screen, under the presentation material tab. The survey will be shown after “click here for survey” button. We would appreciate your cooperation.

Now, we will begin the presentation. President Iwai, please begin.

Iwai: Thank you very much for taking time out of your busy schedule today to attend Fuji Pharma's financial results briefing for the second quarter of the fiscal year ending September 30, 2024. I would appreciate your cooperation till the end.

Now let me move on to the explanation. Today, I would like to explain the contents described here in order.

First of all, I would like to explain the business environment in which we are currently focusing our efforts, and how we are positioned in this environment. Based on this, I would like to give an overview of the consolidated financial results for H1 of the fiscal year and the revised plan for the full year. Finally, I would like to talk about the progress of the developed products.

Currently, we are proceeding with our medium-term business plan in accordance with the four growth scenarios described here. Today, I would like to talk mainly about women's healthcare and biosimilars. But first, I would like to briefly explain the current status of our contrast media business, which is one of our core businesses.

Contrast media currently account for approximately 25% of our sales, or JPY10 billion. This has been addressed during the current medium-term management plan with the goal of making this a sustainable business going forward.

During the period of this medium-term management plan, we have already completed the change of raw material suppliers for the purpose of cost reduction and stable supply. In addition, as I will discuss later in the financial summary, as a result of the approval of the unprofitable repricing of contrast media drug prices, drug prices are now approaching a level that will allow us to continue our business.

In addition, a new contract manufacturing project for contrast media, aimed at improving the production capacity utilization rate of contrast media, is now taking shape, and our transformation into a sustainable contrast media business is currently progressing as planned. I will not discuss the contrast media business and the overseas business today, but if you have any questions in conjunction with them, I would be happy to answer them during the Question & Answer session.

Now, I would like to discuss the today's main topics. First, I would like to talk about the business environment in the women's healthcare.

In terms of policy trends in the area of women's health care, we have summarized here the past administrative actions, along with the economic losses caused by women's health issues announced by the Ministry of Economy, Trade and Industry in February of this year. There are two main points I would like to make here.

The first point I would like to mention is that awareness of women's health issues is increasing annually, and addressing this issue is becoming more urgent and important than ever before. The second point is that our company's role in this context is becoming even more significant.

As far back as 1985, a long time ago, the Equal Employment Opportunity Law was enacted, but since then, there has been virtually no progress in creating a working environment for women. This was the situation. On the other hand, Japan is facing an unprecedentedly low birthrate and an aging population at a rapid pace. The decrease in the number of people who could be in the labor force is becoming a major issue.

To solve both of these problems, Act on the Promotion of Women's Active Engagement in Professional Life was enacted in 2016. As an overview of this project, we aim to create an environment where women can work comfortably by visualizing related information and eliminating disparities in working conditions between men and women. Simultaneously, we will promote reforms in men's working styles and attitudes to foster an environment where women can be even more active in society. These are the objectives.

Comparing the current situation to that of 2016, when the law was enacted, and earlier years, we see that while women have made further advances in society, challenges still remain in the working environment related to childbirth and child-rearing. It is important than ever to create an environment in which women can play more active role in society.

Regarding solutions, there are various actions that need to be taken, and we recognize that addressing women's health issues is one of the most important among these. Based on this, the government has launched a series of policies, as those listed here, since 2016.

As a result of increased awareness of diseases among women and technological innovations, the women's healthcare market is expanding more than ever. However, it is still not sufficient. According to this year's report by the Ministry of Economy, Trade and Industry, the economic loss due to women's health issues is approximately JPY600 billion for menstrual complications, and JPY1.9 trillion for menopausal disorders. And infertility treatment causes an economic loss of about JPY300 billion. The total economic loss is estimated at JPY2.7 trillion.

In particular, the menopausal symptoms shown here, and in the area of infertility treatment, the number shows women who are retiring is still very high. In light of this situation, we consider women-specific issues

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such as dysmenorrhea, menstrual complications, menopausal disorders, and infertility treatment to be important issues to be addressed.

In addition to these three areas, I would like to explain the market for oral contraceptives.

Before I get down to details, I would like to introduce a few of our current initiatives. We are currently working to create an environment in which women can work comfortably by providing support for infertility treatment, medical assistance for treatment of menstrual complications and menopausal disorders and promoting maternity leave for male employees.

When we talk to our business partners about these initiatives, we are often told that they would like to consider them for their companies. We are hoping that this movement will be spreading widely to domestic companies.

Now I would like to return to the main topic. The slide summarizes the market by women's healthcare area and by disease. In the previous slide, I talked about the economic losses announced by the Ministry of Economy, Trade and Industry. The areas mentioned by them are exactly the areas we are currently focusing on.

In the women's healthcare market, awareness of challenges related to female-specific illnesses has increased. As a result, many women who were previously unaware of their conditions are now becoming more conscious of their diseases. According to a survey by Fuji Keizai, the market is expanding at an annual growth rate of about 5%.

The market with oral contraceptives' market added to the market, which includes the three areas of menstrual disorders, menopause, and infertility treatment as mentioned in the METI announcement, accounts for approximately 65% of the total women's healthcare market. Today, I would like to discuss the market for each of these four areas where we hold the largest market share. I will also explain how our products are positioned within each market, specifically focusing on the oral contraceptives market, and the menopausal disorders market where we launched the F-meno capsule the year before last.

And the fertility market where our UTROGESTAN is used. Regarding this area, I would like to discuss the transvaginal luteal support market for now. I will explain in this order, and then in Chapter 4, I plan to discuss dysmenorrhea, which is a significant market alongside endometriosis and uterine fibroids in the women's healthcare market. We will also cover the development of FSN-013, which we hope will become a major contributor to our top line.

Let me begin with the market for oral contraceptives. The table shows the evolution of the oral contraceptives market from 2016 to 2023, as well as our market share in this market.

There are three main points I would like to talk about in this slide. The first point to note is that since oral contraceptives were approved in Japan in 1999, awareness of their use has gradually increased. Additionally, with the expansion of online medical services, the barrier for women to visit obstetricians and gynecologists has been somewhat reduced in recent years, or rather, a system has been established to remove this barrier. Consequently, the usage of oral contraceptives is on the rise.

Another point is that we are the only company in Japan to have two oral contraceptive products, and this has been a strength that has helped us expand our market share. This is the second point.

On the other hand, when we compare the Japanese domestic market with that of Europe and the US, the domestic penetration rate is still only 9%, and compared to markets in Europe and the US, such as 33% in France and 14% in the US. We can see that there is still much room for expansion.

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Next, I would like to look at the market for menopause and fertility treatment. In the menopausal market, we launched F-meno capsules in November 2021, the first progesterone preparation in Japan indicated for the treatment of menopausal symptoms. Since then, the market for menopausal treatment is expanding.

According to the Ministry of Economy, Trade and Industry survey as I mentioned earlier, economic losses due to menopausal disorders amount to JPY1.9 trillion. We believe that treatment of menopause as a disease is becoming more important than ever before.

Hormone replacement therapy has become the standard of care in Europe and the US, accounting for more than 20% of all treatments for menopausal disorders due to its high efficacy, but the rate of use in Japan is still less than 5%. Considering these circumstances, we believe that the area of menopausal disorders drug will also expand in the future, and that this is a market in which we should contribute even more.

Regarding the infertility drug market in the lower bottom, I would like to focus on mentioning about the market for transvaginal luteal support products, as mentioned earlier. The market for infertility treatments has rapidly expanded following the introduction of insurance coverage in April 2022. Compared to Europe and the US, Japan has always had an active market for fertility treatments, and we believe that the level of activity seen in 2023 will continue in the future.

Our product UTROGESTAN, a transvaginal progestin, experienced a significant increase in sales last year in 2023, replacing a competitor's product that was out of stock. This year, we expect results to be roughly on par with the previous year due to the introduction of insurance coverage for infertility treatment and the fact that the impact of shortages of competitors' products will be considerably calmed down. The market share of our product UTROGESTAN already exceeds 40% in this field. We intend to continue to make a strong contribution in the area of infertility treatment.

So far, we have discussed oral contraceptives, menopause medications, and infertility medications. In summary, I believe that all of these markets are on expansionary trends, and that our products occupy an important position in each of these areas.

We intend to continue to work firmly in this area to meet the expectations of our patients. The other important area of dysmenorrhea will be discussed again in Chapter 4 under the section on new products.

Next, I would like to talk about the market environment for biosimilars. The slide shows a summary of policy trends, and I am sure you have heard the term "biosimilars" used frequently these days.

I have two major topics that I would like to discuss today. The first point I would like to talk is what biosimilars are. Currently, about 30% of the global pharmaceutical market is dominated by drugs called biopharmaceuticals, which are the frontrunners. Biosimilars are called bio-successor products to these prior biopharmaceuticals, which means that they are antibody drugs.

While the preceding antibody drug have superior efficacy and safety, it is very expensive are putting pressure on social security costs, and this is becoming a problem. Reducing medical costs by replacing these products with biosimilar will continue to be an important issue in controlling social security costs. This is the first point.

The second point is that the chemical structure of biopharmaceuticals, including biosimilars, is extremely complex and delicate. So, when compared to the development of ordinary generic drugs, the technology required for the development of bio-successor drug is very advanced. The second point is that only a limited number of companies in the world are capable of commercializing biosimilar drugs.

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The structure of the domestic market is similar to that of the global market, with JPY3 trillion of the JPY11 trillion prescription drug market in 2023 being biopharmaceuticals. However, currently most of them are biopharmaceuticals, and biosimilars are still not a large market at JPY120 billion out of that amount.

On the other hand, national healthcare costs have increased 1.5x over the past 15 years in Japan, primary due to the aging of the population, and are expected to continue to increase in the future.

Against this background, the Ministry of Health, Labor, and Welfare (MHLW) indicate specific numerical targets for biosimilars last year for the first time. The goal is to achieve 80% biosimilar replacement rate for 60% of items by 2030. We believe that this will be a great tailwind for the spread of biosimilars, which has not progressed sufficiently until now.

I mentioned that only a limited number of companies are capable of developing and approving biosimilars, and we are one of the few companies in Japan that can do so. On the next slide I would like to explain our advantages.

As I mentioned in the previous slide, biosimilars differ from small molecule drugs used in generics because they have a much larger molecular weight and their chemical structure is extremely complex. Therefore, to obtain approval for biosimilars, clinical trials similar to those required for new drugs are necessary.

Phase 1 trial is required to confirm safety and Phase 3 trial is required to confirm efficacy, and depending on the product, several hundred cases may be necessary.

If we try to develop the product for approval in a single market, such as Japan, it is not easy to secure profit because the development cost is very high for a business in the limited Japanese market. Based on the comprehensive alliance with Alvotech in Iceland, we are promoting a tri-polar simultaneous development system including Japan, in addition to development in Europe and the US. This has allowed us to keep the cost of obtaining approval in Japan low. Another advantage is that Alvotech's production system is designed with global supply in mind, which also reduces manufacturing costs.

In addition, we are currently considering the production of a formulation in the Toyama Plant with a view to secure a stable supply in the future. In terms of the quantitative contribution from the biosimilars business, we expect it to begin from the next fiscal year. However, we are currently making good progress in our efforts to establish biosimilars as the next pillar of our business.

Our current pipeline is shown here. In November last year, we received approval for the first biosimilar of Ustekinumab in Japan, a drug for psoriasis, and the drug is scheduled to be listed on the NHI drug price list in May this month.

We are also planning to apply for three more components during this fiscal year, B, C, and D, which I am covering names. In addition to the three components B, C, and D, we have an agreement with Alvotech for the development of three more products in Japan, so we can offer a continuous lineup of such products. We believe that this is the strength of our tri-polar approach indeed to make a global development together with Alvotech.

Since we are here, I would like to introduce a little about Ustekinumab, which is scheduled to be included in the NHI drug price list this month. This drug was approved last year and only we have marketing approval. In Japan, it will be released independently as the biosimilar 1. We believe that being the only company in the biosimilars 1 is a great advantage, and even if there are 2 or 3 becoming available, we believe that we will be able to maintain our superiority.

These are the policy trends of biosimilars in Japan and our position in light of these trends.

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I would now like to move on to an explanation of the results for H1 of the year. The results of H1 of the fiscal year have already been announced. Net sales increased approximately JPY2.2 billion YoY. EBITDAR, which indicates the ability of existing products to generate cash, increased JPY220 million. This is the sum of depreciation and R&D expenses added back to operating profit.

Operating profit, on the other hand, decreased by JPY380 million due to an increase in R&D expenses and an increase in expenses resulting from the strengthening of the sales structure in preparation for the marketing of Ustekinumab, as mentioned above.

Net income, on the other hand, increased by JPY2.5 billion due to the recording of a gain on the sale of cross-shareholdings last November.

What I have shown you here is a summary of what I have just said. On the other hand, I would like to talk a little bit about the progress on the qualitative side in H1 of the year on the next slide.

The expansion of our overseas business has been lagging far behind when we drew up our medium-term management plan, but it is finally taking shape. OLIC, our subsidiary in Thailand, has successfully completed the FDA inspection for contract manufacturing for the US market and is now ready to begin production upon request from the contractor.

Regarding the challenge of establishing manufacturing and sales at OLIC, or making it a full-line operation, the expansion in Asia, centered on Nextstellis is now making concrete progress.

In Toyama, the Toyama Plant and Toyama Research Institute are currently working with a partner company in the US on a specific project to develop a formulation and are now in the process of preparing a clinical formulation.

As for generics, we launched a new product, LENALIDOMIDE capsules “F” in January this year. In February, we began selling LANDIOLOL HYDROCHLORIDE for hydrochloride intravenous infusion, which is now our sole product. In February, we also received approval for SUGAMMADEX for intravenous infusion, and are now preparing to launch the product.

As stated here, I believe that the results of the H1 of the fiscal year were a significant to make preparations for the future of generics.

I would now like to explain in more detail the changes in sales and operating profit for the H1 of the year.

First of all, sales increased by JPY2.2 billion compared to the same period last year, and there are two main reasons for this increase. One is the progress of our main products in women's healthcare. This was due to the market penetration of F-meno capsules, which were launched in November 2021 and are used in the treatment of menopausal disorders. The other is DOXIL, a cancer drug used in the treatment of ovarian cancer. DOXIL is a product of Baxter Corporation of the US, with which we began a sales partnership last year.

As I mentioned at the beginning in the section on contrast media, there is also the increase in drug prices due to unprofitability. As a result of repricing of some products including contrast media and Iopamidol, the prices were close to the appropriate prices to maintain a stable supply, which contributed to the sales of these products.

These two reasons I just mentioned are the increase compared to the previous fiscal year.

On the other hand, while gross profit significantly increased due to sales growth compared to the same period last year, operating profit decreased due to an increase in personnel expenses related to the sales of the

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Ustekinumab biosimilar, which was approved in November 2023. Prior to approval, we formed a team specializing in psoriasis and a marketing team to develop sales strategies. We also assigned dedicated personnel to each area in Japan to directly approach medical institutions after the approval, resulting in an upfront increase in personnel expenses related to the sales of the Ustekinumab biosimilar.

The necessary market research has been completed, and a system is now in place to promptly begin sales once the NHI drug price is listed on the NHI drug price list.

In addition, although operating profit decreased for H1 from the previous year due to the increase in R&D expenses associated with new projects that explained earlier, EBITDAR increased by JPY200 million from the previous year, as shown on page 17.

Regarding the deviation from the plan set at the beginning of the fiscal year, the main reason for the shortfall this time is that the market penetration of the main products listed here was delayed from the initial plan to H2 of the fiscal year due to various reasons.

For F-meno capsules, the acquisition of prescriptions from menopause specialists is progressing steadily and sales have increased compared to the previous year. However, the acquisition of prescriptions from non-specialists have not proceed as initially planned, resulting in a shortfall compared to the plan at the beginning of the fiscal year.

As mentioned earlier, we expected the demand for UTROGESTAN from the previous year to continue this year. However, our sales will return to normal after temporarily expanding in 2023 due to a shortage of competing products. Although our market share has been maintained at 40% or more, sales did not meet the planned targets.

For oral contraceptives, we have planned to meet demand through increased production at the new formulation facility. However, we have not met the initial plan for the period due to the time needed to confirm the quality of products manufactured in the new facility and then a pause in aggressive sales activities.

The main reason for the decrease in operating profit is the decrease in gross profit due to the shortfall in sales, as I mentioned earlier. Although there was a slight positive effect from the postponement of R&D expenses from H1 to H2, it fell approximately JPY500 million short of the plan at the beginning of the fiscal year in H1.

Next, I would like to talk a little about the balance sheet and cash flow. There is no significant change in the balance sheet. The repayment of some long-term debt has improved the equity ratio by about 3.5 percentage points.

Cash flow decreased by approximately JPY1.0 billion from the end of September last year due to the repayment of long-term debt, as I mentioned earlier.

I would now like to explain our revised consolidated plan for the full fiscal year ending September 30, 2024. Before I explain the full year, I would like to begin with an overview of H2 of the fiscal year.

In H2, sales are expected to increase by approximately JPY3 billion YoY due to penetration of the three products in the women's healthcare field will progress, which had a slow start in H1. It may be a little confusing, but the first two arrow feathers on this slide here show the reasons for the JPY3 billion increase compared to the same period last year. The other two are the reasons why sales for H2 of the fiscal year will be JPY580 million less than planned at the beginning of the fiscal year.

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For H2 alone, sales of oral contraceptives are expected to fall slightly short of the plan at the beginning of the year, but sales of other major products are expected to be in line with the plan at the beginning of the year in the second half.

In addition, I would like to make a few additions to this fourth arrow feather, the decrease due to test production efficiency. Toyama plant undertakes contract manufacturing for other companies. In the new contract manufacturing project, the number of test production lots initially assumed to be several was successfully reduced. This streamlining was achieved by revising the required number of lots in collaboration with the contract manufacturer, focusing on the pharmaceutical affairs strategy.

This resulted in a decrease in sales due to a reduction in the number of lots required for test production. Therefore, the new contracts and manufacturing projects themselves are currently proceeding as planned and will have no impact on our business performance in the next fiscal year and beyond.

Operating profit also decreases in line with the decrease in sales. Based on the above, our plan for H2 of the fiscal year is as follows.

Sales and operating profit are as explained on the previous slide. Although decrease in new contract manufacturing projects and sales of oral contraceptives fell slightly short of the initial plan, sales of other mainstay products in H2 of the year are expected to be in line with the plan at the beginning of the fiscal year.

EBITDAR, which indicates the ability of existing products to generate cash, continued to increase in H2 of the year, will increase by JPY1.3 billion from the same period last year.

The revised plan for the full year, taking into account the situation in H2 of the year, is shown on the next slide. I have written this in writing, but if I were to summarize it numerically, it would be as shown in the next slide.

Net sales will increase by JPY5.2 billion YoY and EBITDAR increase by JPY1.5 billion for the full year. Operating profit will increase by JPY130 million due to an increase in R&D expenses and personnel expenses associated with preparations for the launch of Ustekinumab. And net income will increase by JPY2.7 billion due to the gain from the sale of investment securities last November.

As I mentioned earlier, we plan to maintain the same level of sales for our mainstay products in H2 as planned at the beginning of the year, with the exception of oral contraceptives. The revised plan for the full year also projects an increase in sales and profit compared to the same period last year.

That is all for now, but I would like to discuss the revised plan for sales and operating profit in more detail in comparison with the previous fiscal year.

Looking at the full year, women's health care will see an increase of JPY2.86 billion over the previous year. Full-year contribution of DOXIL, a drug for ovarian cancer treatment, for which we acquired the marketing rights in the previous fiscal year. Additionally, there is the contribution of Estradiol, a follicle hormone used in menopause treatment, which was approved and launched as a new generic product in the previous fiscal year. As for F-meno capsules, we are making steady progress in obtaining prescriptions from non-specialists where we have not been able to obtain prescriptions as planned.

And PROPESS. This is a drug used in the perinatal period, an area where no new products have been launched in more than 10 years. It is now gradually penetrating the market as a new drug for childbirth and is expected to make a contribution.

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As for UTROGESTAN, for which did not meet the plan in H1, there is no change as the calming down of the market has been incorporated into the plan for H2. As for oral contraceptives, as I mentioned earlier that it is taking time to confirm the quality of the new formulation facility, we have established a system to increase production at the existing formulation facility, and we are now in a position to respond to demand.

The other major point is that in acute medical care, YoY increase was mainly due to the acquisition of unprofitable repricing, such as contrast media and DEXART in acute medical care, and HMG in women's healthcare, as forecasted at the beginning of the period.

The total of these positive and negative factors is projected to increase revenues by JPY5.1 billion from the previous year.

Gross profit is expected to increase by JPY1.9 billion due to the increase in sales compared to the previous fiscal year. But operating profit is, as already explained, we expect an increase of JPY130 million due to the strengthening of the information provision system for the new product Ustekinumab, as well as the increase in R&D investment described here.

In the next two slides, I would like to explain the most recent R&D expenditures and EBITDAR. Regarding R&D expenses, we are currently shifting to a development of high value-added products. As a result, we have been increasing our R&D expenditures every year, and as reported in the previous highlight, the number of newly approved items has also increased concretely as a result.

In addition, we are making concrete progress in the development of new drugs for the US market, and we are now beginning to see the results of our efforts. In particular, we expect to spend slightly more on R&D this fiscal year than we did at the beginning of the fiscal year due to up-front investments in new initiatives, as described here.

Next, EBITDAR, which represents the cash generated by existing products, is calculated by adding back depreciation and R&D expenses to operating profit. EBITDAR is growing steadily, a result of the market expansion and increase in our market share as previously explained. This indicates that our ability to generate cash has expanded as you can see.

We will continue to develop new products while measuring the balance between market penetration of our core products and investment in the future.

Next, the last slide in Chapter 3 shows that although operating profit has decreased compared to the plan at the beginning of the fiscal year, the interim dividend of JPY20 has already been resolved and is as announced. For the full year, the annual dividend will remain unchanged at JPY42.50 per share.

Now I would like to conclude with a discussion about development progress in Chapter 4. As for development products, I would like to discuss the market trend of dysmenorrhea and our newly developed product, FSN-013, which I mentioned in Chapter 1.

Market as a whole, as I mentioned at the beginning of this presentation, the dysmenorrhea market is one of the largest fields in women's healthcare.

Comparing the five-year period from 2017 to 2023, the bar graph on the left shows that the number of sheets used has expanded rapidly by about three times. As shown in the figures on the right, the NHI price base has doubled despite the devaluation of NHI prices and the entry of generics into the market.

According to IQVIA's NHI price-based data, the total market is approximately JPY40 billion, making it one of the largest markets in the field of women's healthcare today.

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As I mentioned at the beginning of this presentation, the Ministry of Economy, Trade and Industry (METI) estimates that the economic loss caused by neglecting this disease is approximately JPY600 billion per year due to menstrual complications, and we recognize that this is another area in which we should make further efforts.

In 2008, we began marketing Lunabell, a drug for dysmenorrhea. We had been leading the dysmenorrhea market, however, sales of Lunabell has almost disappeared as a result of the launch of Lunabell's AG and generics from other companies, unfortunately. In there, we are going to introduce FSN-013 as an innovative formulation containing Estetrol.

As already reported, FSN-013 was submitted for approval last October and is currently in the approval review stage. Although existing estradiol and progestin products are widely available, the rare occurrence of thrombosis remains a concern for both physicians and their patients.

The bottom row shows the comparative data of D-dimers in FSN-013 and placebo. The D-dimer is a clinically useful indicator for evaluating patients with suspected thrombosis. An elevated D-dimer value indicates an increased risk of thrombosis.

Although existing estradiol-containing products have been reported to increase D-dimer levels, the data shown here for FSN-013 in comparison with placebo indicate that D-dimer levels are unchanged in FSN-013 compared with placebo.

We expect that this will be an innovative drug to reduce the risk of thrombosis, a side effect, compared to existing drugs. We plan to firmly deliver the product to patients and develop it into our next top product. As for the timing of the market launch, we are expecting it by the end of this year.

Finally, this is a summary of our pipeline. In the field of women's healthcare, as I mentioned, FSN-013 is currently under review. In addition to this, we will continue to study the menopause treatment area, and at the same time, we will have a solid lineup of biosimilars. This is what we are trying to do.

As for biosimilars, we plan to submit applications for three additional biosimilars (B, C, and D) in the current fiscal year. These are the status of developed products.

Finally, here is a summary. As for the current fiscal year ending September 30, 2024, although we are currently making steady progress in the development of new products, there is a delay in H1 comparing to the plan. However, we expect H2 to be almost in line with the original plan at the beginning of the fiscal year, so the revised plan for the full year is expected to increase sales by JPY5.2 billion and operating profit by JPY130 million compared to the previous year.

It took a while, but I would like to conclude my explanation now. Thank you for your attention

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Question & Answer

Takasaki [M]: Thank you for your explanation. We will now move on to the Question & Answer session. If you have any questions, please enter in the comments field on the screen.

Moderator [M]: I will guide you on how to send the chat. If you are participating online from a computer or other device, there is an area below the video where you can enter your message. After entering the information and clicking the submit button, the information you have entered will be displayed and the submission will be completed.

If you are participating online from a smartphone, scroll down to the bottom of the screen to the field. A way to send is the same.

We look forward to receiving your messages.

QUESTIONER [Q]: I have a first question. I would like to know about the target sales and market share of Ustekinumab. I believe that the presence of biosame is a stumbling block for the spread of biosimilars. Please also tell us regulation situation for biosame.

Iwai [M]: Thank you very much. Morita would like to answer your question.

Morita [A]: Morita will answer. Regarding the questions, I believe we received two questions. One regarding sales and market share of Ustekinumab, and the other is regarding to biosame.

First of all, we will not disclose the sales and market share of Ustekinumab but let me explain the marketability of Ustekinumab. The market for the prior biopharmaceuticals for Ustekinumab is more than JPY60 billion based on the NHI prices. The two major indications are psoriasis in the dermatological field and Crohn's disease and ulcerative colitis in the gastrointestinal field. Its market share is 1:9 in dermatology versus gastroenterology.

First of all, our biosimilar, which is scheduled to be launched in May, is only indicated for psoriasis in the dermatological field. So, its target market is 10% of the total market for the preceding product. Therefore, we believe that the target market is not that large and will not have a significant impact on our business performance in the current and next fiscal years.

On the other hand, as President Iwai explained earlier, we are the first and only one company to obtain this approval. So, we can start our activities as the first biosimilar manufacturer. We have set up a dedicated organization for psoriasis even before approval. Now we are currently in the process of recruiting after approval. It will be important to conduct activities to secure an account in the psoriasis area.

By securing the accounts, even if the second biosimilar product comes out later, two biosimilar products are rarely adopted by hospitals at the same time in this biosimilar field. So, in that sense, we will firmly increase the number of accounts as the first biosimilar product, Ustekinumab.

When the indication is expanded to the gastrointestinal field, which will probably be several years from now, it should make a solid contribution to sales.

Regarding the second question, biosame, as you pointed out, it is not necessarily positive for biosimilars. We will continue to closely monitor the trend of biosame.

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On the other hand, there has already launched product as a biosame, Darbepoetin, in Japan. Whether biosame is necessarily strong or not, biosimilars have also gained a certain market share. So, we are conducting a thorough analysis of their contents.

In our product development, we have considered from the beginning that some products may be available as biosame. We will make thorough preparations to compete with these products using our own biosimilars.

These are the answers to your questions.

Questioner [Q]: Thank you. Now for the next question. This fiscal year is the final year of your medium-term management plan. What are your sales targets for women, biosimilars, overseas, and contrast media?

Iwai [M]: Thank you very much. We would like to explain each of them, referring the Appendix. Morita will explain in some detail.

Morita [A]: Then, I would like to turn to page 43 of the Appendix. Here are the results for each business area and the revised plan for the current fiscal year.

The rightmost column shows the revised plan. First of all, we expect to achieve JPY20.9 billion for women's healthcare, compared to the target of JPY20 billion set in the current mid-term plan.

As for overseas business, we had set a target of JPY9 billion at the time of preparation of the medium-term business plan. We expect to reach JPY3.8 billion in this area. This is due to delays in contract manufacturing projects at the Toyama Plant by OLIC for the US market, and in Asean for selling FSN-013 in Thailand under the name Nextstellis, among others.

As for contrast media and biosimilars, please refer to page 45. As for contrast media, if you look at the rightmost figure, the plan was for JPY11 billion when the medium-term management plan was prepared. Now, the figure is JPY10.1 billion, which is generally in line with the plan.

As Iwai mentioned, the plan for biosimilars itself was small at JPY2 billion when the mid-term plan was planned. The estimated landing amount for the current fiscal year is JPY1.8 billion. The past five years have really been a period of preparation for the next five years, and we are now entering a phase of business expansion.

These are the answers to your questions.

Questioner [Q]: Thank you. The next is your last question. I have three questions.

You have announced a downward revision this time. I think it deviates considerably from the 2030 Vision. Are you planning to make any updates to the next medium-term plan or the 2030 vision?

Regarding the plan for R&D expenses for FY2024, I see an increase in R&D expenses in H2 due to the development of high value-added products. Which area are you talking about?

Is there any update on the progress of FSN-014?

I would appreciate your answer to these three questions.

Iwai [A]: Thank you very much. I will answer.

In response to your question about any updates to the 2030 Vision, as Morita just explained, the response to overseas markets is a major factor in the underachievement of the current medium-term plan

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Although there has been a slight delay in this area, it is now taking shape. We intend to catch up by making a concrete progress in the next medium-term management plan.

The current medium-term management plan will end in the fiscal year ending September 30, 2024, we are currently preparing the next plan, which we will explain to you as soon as it is ready.

Regarding the second point, the development of high value-added products, we currently define high value-added products as the development of new drugs and biosimilars. Of course, we will continue to develop generics, but we are now shifting to the development of high value-added products. This is our main trend.

On the other hand, the increase in R&D expenses for the current fiscal year is due to higher development costs for a new formulation for the US market, which is currently being studied in detail at the Toyama Research Institute and the plant. This is the most significant factor.

As for the progress of FSN-014, the licensing company is in the process of submitting an application for approval in the US and Europe. Once the approval is obtained, we will proceed to examine how to bridge the gap between the data and Japan in order to progress the development and make it realize.

We would like to provide an update once we have received approval from the US and Europe. I have answered the above.

Takasaki [M]: Thank you very much. We received many questions, and we apologize for not being able to answer all of them. If you have any questions after the briefing, please contact the Corporate Planning Department as indicated in the presentation materials.

Finally, we would like to ask a favor of those who participated. Please send us your feedback of today's online financial results presentation by filling out the questionnaire. The survey can be found on the bottom of screen in the presentation materials. Please click “survey is here” button to display.

The questionnaire will also be sent via email after the briefing. We would appreciate your cooperation.

This concludes the presentation of the financial results for the second quarter of the fiscal year ending September 30, 2024, of Fuji Pharma Co., Ltd. Thank you to everyone who stayed with us until the end.

[END]

Document Notes

1. *Portions of the document where the audio is unclear are marked with [Inaudible].*
2. *Portions of the document where the audio is obscured by technical difficulty are marked with [TD].*
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