Presentation

Moderator: Hello, everyone. Thank you very much for joining us today for the financial results briefing for the fiscal year ending September 30, 2023 of Fuji Pharma Co., Ltd.

I would like to introduce today’s speaker from the Company. Mr. Takayuki Iwai, President and CEO.

Iwai: Thank you.

Moderator: Mr. Shuhei Morita, Executive Corporate Officer, Corporate Strategy Division, Head of Corporate Planning.

Morita: Thank you.

Moderator: Mr. Masayuki Naganawa, Executive Officer, Deputy General Manager of R&D Division.

Naganawa: Thank you.

Moderator: Now, to proceed with today's proceedings, the Company will explain the summary of financial results for the fiscal year ending September 30, 2023, and the consolidated earnings forecast for the fiscal year ending September 30, 2024. We will then proceed to the Q&A session. The Company 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.

The Company will be happy to receive questions via chat even during the presentation. The Company also ask for your cooperation in completing a survey to help us in the future IR activities. The survey is located at the bottom of the screen under the Explainers, Slash, and Resources tabs. Please click here to view and complete the survey.

We will now start the financial results briefing. President Iwai, please go ahead.

Iwai: Thank you very much for taking time out of your busy schedule today to attend Fuji Pharma's financial results briefing for the fiscal year ending September 30, 2023. Thank you for your cooperation until the end in advance.

Today, I would like to present an overview of the previous fiscal year, ending September 30, 2023, as well as our earnings forecast for the fiscal year ending September 30, 2024, the final year of our medium-term management plan.

First, let me give you an overview of the consolidated financial results for the previous fiscal year, ending September 30, 2023. The numerical results will be explained in detail on the following slides, but the previous fiscal year ended September 30, 2023, was a year in which the preparations we had made to date began to produce results in both quantitative and qualitative terms.

Here is a brief summary. In the previous fiscal year, sales of women's healthcare products grew significantly. The growth in OLIC's performance also contributed on a consolidated basis, enabling the Company to end the fiscal year with higher revenues and profits compared to the fiscal year ending September 30, 2022.

In addition, significant progress was made in research and development. The first is FSN-013, which we expect to be a product that will support the next growth of our women's therapeutic area, and we were able to

submit the application in Japan as scheduled. The other was the approval of the biosimilar, ustekinumab, for manufacturing and marketing in September of this year as planned.

Now, from the next slide, I would like to explain the results for the fiscal year ending September 30, 2023, focusing on 3 areas: women, overseas, and research and development.

First, sales increased by JPY5.4 billion compared to the fiscal year ending September 30, 2022, due to steady growth in women's healthcare products. Consolidated results and sales reached a record high of JPY40.9 billion as a result. On the other hand, operating income increased by only JPY80 million due to an increase in R&D expenses associated with the application for FSN-013, but EBITDAR increased by JPY1 billion from the previous year, showing a steady increase in profitability.

I would like to explain on the next slide the main factors behind the increase in revenue and profitability in the previous fiscal year.

The breakdown of the JPY5.4 billion revenue increase is shown here. The names of the products are listed here, but please refer to page 12 for the sales of each product for the previous year.

In the area of women's health care, sales of oral contraceptives increased by only JPY160 million, but sales of F-meno capsules, progesterone used in hormone replacement therapy for which a new drug was approved in September 2021, totaled JPY2.75 billion for the year, an increase of JPY2.0 billion from the previous year.

In addition, Utrogestan also increased by JPY1.4 billion from the previous year to JPY2.6 billion for the full year, and our new drugs have been steadily penetrating the market.

In addition, we have entered into a new sales agreement with Baxter of the U.S. for Doxil, a drug for ovarian cancer. This contribution resulted in an increase of JPY1.3 billion.

In addition, OLIC, which I mentioned at the beginning of this report, increased its sales by JPY600 million, resulting in consolidated sales of JPY40.9 billion for the fiscal year ending September 30, 2023.

I just mentioned the comparison with the fiscal year ending September 30, 2022, but if we compare this with the original business plan, we saw a large increase in sales of Utrogestan for infertility treatment compared to the plan, but sales of F-meno capsules and oral contraceptives fell short of the plan.

The oral contraceptives fell far short of the plan because we were unable to deliver the required quantities to patients in the required quantities due to delays in the start-up of the new plant that manufactures these products. Since the start-up of this new plant has been completed, we are now well-positioned to deliver the required sufficient volume in the current fiscal year ending September 30, 2024.

Although the market penetration of F-meno capsules increased by JPY2 billion over the previous year, there was a slight delay compared to the plan. We have already begun to implement measures to deal with this delay of JPY750 million, and we plan to deliver them to patients in the current fiscal year.

I would like to go back a little bit to the past to discuss the process I have just described.

As you can see in the upper part of the chart, the amount for women's healthcare was JPY10.8 billion for the fiscal year ending September 30, 2020, the first year of the medium-term management plan. The Company's sales accounted for 32% of the total sales of the Company, but since the sales grew to JPY18 billion in the previous fiscal year, it now accounts for a large 44% of the total sales of the Company.

I think we can see that over the next 4 years, the shift to a specialized pharmaceutical company, specialized in this area has progressed even further.

On the other hand, in the field of acute care medicine, especially contrast media, we have been making steady progress in the last fiscal year in turning this into a sustainable business for our Company as an essential drug. The bottom row shows the ratios by dosage form, which we hope you will refer to again separately.

Now, I would like to talk a little about the position of our women's healthcare business in Japan on the next slide.

This is the total market in Japan, and the total market for women's healthcare in 2020 is JPY72.8 billion. The forecast for 2023 is JPY91.2 billion, which represents an annual growth rate of about 8% for the market as a whole.

Under these circumstances, we are currently in the process of transforming ourselves from a generic-oriented company to a specialized pharmaceutical company, strongly focusing on the area of women's health. The results of these efforts can be seen in the figures here.

Our growth rate in this sector averages 18% per year, compared to an average market growth of 8%. And our share of this total has increased from 15% to 20%.

There are 2 main factors contributing to the overall expansion of the market. One is that women are entering the workforce more than ever before. Then there is the growing health consciousness. Another is insurance coverage for infertility treatment. These are the main reasons.

Here, we are able to serve patients and medical institutions by providing both new drugs and generics, with a solid lineup of medicines that are needed by patients of all ages. We believe that the results are reflected in these figures.

Please refer to the next slide, page 12, which shows sales by each product.

I would like to talk about the points I just mentioned, and what kind of movements were taking place in a few different areas in the field of women's health care.

The upper row here is by area. This is women's health care by area. Comparing this to the fiscal year ending September 30, 2020 and the fiscal year ending September 30, 2023, infertility treatment product sales increased from JPY2.8 billion to JPY4.7 billion in 4 years. Then, oral contraceptives from JPY2.4 billion to JPY3.8 billion. In the area of drugs for menopausal disorders, we launched F-meno capsules at the end of 2021, and the sales amounted to JPY3.2 billion, up from JPY400 million.

We believe that this is a result of our efforts to deliver products that are needed by patients. Last year, the market for infertility treatments and the market for menopause treatments were 2 areas in which our products grew significantly. I would like to explain a little more about our Company's situation in these areas.

Although the lower part of the slide focuses on the acute stage, I would like to point out that we are steadily transforming into a sustainable business in the acute stage medical field, especially in contrast media, as a supplier of essential pharmaceuticals.

These are the 2 areas in which we achieved significant growth last year, as I mentioned earlier. Here, we picked up the market segments for infertility treatments and menopause treatments, respectively.

With the introduction of insurance coverage, the overall market for infertility treatments is expected to expand from JPY13.3 billion in 2020 to JPY17.1 billion in 2023, with an average market growth rate of approximately 9% during this period. In this context, the average growth rate of our Products and the average growth rate over the 4-year period is about 19%, which means that we have added to the market growth, and in this context, we have been able to deliver the necessary drugs to patients well. We believe that is the result. As a result, our market share, which was also 21% in this market, is now confirmed to be 28%.

On the other hand, in the menopause treatment market, the annual growth of the market as a whole over the past 4 years has been limited, at JPY5 billion per year, but our presence in this field has increased considerably since we obtained approval for F-meno capsules in 2021 and began delivering them to patients. We believe that the market for drugs to treat menopausal disorders is one in which we should make a greater contribution to patients in the future. I will touch on this in more detail in the second chapter that follows.

As I mentioned so far, this is a list of the top 15 products in terms of sales, of which 9 are in the field of women's health care. We believe that this is the result of our Company's progress in becoming a specialized pharmaceutical company in this field.

Now I would like to move on to our overseas business.

I would like to divide our overseas business into 2 major segments: ASEAN and the U.S. business.

In the ASEAN region, the OLIC contracting business, which is a traditional business, has been growing along with the expansion of the ASEAN market. This, combined with the effect of a weaker yen, resulted in a 21% increase over the previous year.

In April of this year, we also began full-scale sales of a new follicle hormone pill called E4, which is the same as FSN-013, which I will explain later. The photo on the right shows the launching event held in Bangkok at that time, which was attended by about 200 doctors in Thailand, showing great interest in this product.

On the other hand, in the U.S., both OLIC and Fuji Pharma have started to make progress on specific projects. OLIC is now making concrete progress in the contract business for injectable drugs for the U.S., and has just completed a pre-approval inspection by the FDA in March of this year.

In Japan, we have formed an alliance with a partner company of the U.S. and started development of a new drug in the field of women's medicine specifically last fiscal year. Since the time when the medium-term management plan was formulated, we have been slightly behind schedule in our overseas business, but last fiscal year we began to make concrete progress on specific projects.

These are the overseas operations.

Next, I would also like to talk about new product topics.

In the last fiscal year, there were several progresses as shown on the slide here. FSN-013, which we expect to be the next top product to support our women's healthcare business, was submitted for marketing approval in October this year as planned.

In the area of biosimilars, we received approval for ustekinumab in September. We have also obtained approval for 2 generic products.

As I mentioned earlier, the new product is estradiol which is used in the market of drugs for menopausal disorders, an area in which we will be focusing more attention in the future. The product, written at the

bottom of this slide, an estradiol tablet, which is a follicle hormone, was also launched in the previous fiscal year.

This quantitative impact will also be significant to a certain degree in the fiscal year ending September 30, 2024, and I would like to discuss it later in the explanation of the business plan for this fiscal year.

I would like to discuss in more detail about FSN-013, which we have applied for as a treatment for dysmenorrhea, such as the overview of the product or its market, in our plan for the current fiscal year.

Finally, the balance sheet shows that current assets and fixed assets increased by a total of JPY10 billion for the reasons described here.

As for cash flow, operating cash flow increased by JPY2.5 billion compared to the fiscal year ending September 30, 2022. Then there was a JPY6 billion increase in investment cash flow. Financing cash flow decreased by JPY3.0 billion.

These are the explanation of the results for the fiscal year ending September 30, 2023.

Next, I would like to talk about the consolidated earnings forecast for the current fiscal year ending September 30, 2024.

In the previous fiscal year, I mentioned that the fiscal year ending September 2023 was a year in which we finally began to see results from the preparations we had made up to that point. We believe that the fiscal year ending September 2024, the final year of our medium-term management plan, will be a year in which this will be further materialized.

Net sales increased by JPY8.0 billion from the previous year to JPY49.0 billion as sales of products in the women's medical field mainly grew. And we plan to increase operating income by JPY1 billion to JPY4.9 billion. EBITDAR and EBITDA, as shown on this slide, are JPY11.8 billion and JPY8.7 billion, respectively, both up JPY2.0 billion from the September 2023 period.

As I mentioned earlier, the key to achieving our business plan for this fiscal year lies in whether or not we can make a solid contribution to patients in the field of women's healthcare. Today, I would like to explain the contents of this term's plan, with emphasis on this point, from the next slide.

The graph on the left here shows the breakdown of the JPY8 billion increase I mentioned earlier. The area of women's health care will increase by JPY5.7 billion, which can be roughly divided into 3 categories.

First, in the area of oral contraceptives, the increase in the previous fiscal year was only JPY160 million due to the delay in the start-up of the new plant, but production at the new plant will be in full swing during the current fiscal year ending September 2024. Therefore, unlike the previous fiscal year, we expect a steady increase in the oral contraceptive field because we will be able to deliver the necessary quantities to patients who really need them, without restricting supply.

As for the products in the menopause market, hormone replacement therapy, one of the treatment methods for menopause, uses 2 hormones, follicular hormone and progesterone. On slide 14, in the section on our new Products, I mentioned that we launched estradiol last fiscal year.

This will be the follicular hormone used in hormone replacement therapy. This means that estradiol is expected to make a certain quantitative contribution this fiscal year by contributing for the full year.

The other progesterone, F-meno capsules, was about JPY750 million behind plan in the previous fiscal year, but the understanding of this product among doctors at medical institutions is steadily progressing, and prescriptions for use in the medical field and for patients are steadily increasing. The situation is now such that an increase of approximately JPY1 billion is expected here.

In the third category, we have products for infertility treatment, such as Utrogestan, HMG, and Folyrmon, which are our main Products used for infertility treatment, and which are needed more than ever by patients after they are covered by the insurance. We expect an increase in the number of these products this fiscal year.

As for the women's area, it is as I just mentioned. In addition, please refer to the breakdown of the JPY1.7 billion increase in the middle of the graph.
The new contract business that we have been working on at the Toyama Plant for about 3 years will take shape from this fiscal year.

Also, OLIC's new CMO business is progressing well along with the recovery of the ASEAN market and is planned to increase by JPY8 billion from the previous fiscal year to JPY49 billion.

Let's take a look at what I have just said, again organized by area, as shown here.

In the women's area, the total for the full year is JPY23.7 billion, an increase of JPY5.7 billion from JPY18.0 billion in the previous year. Then there is JPY17.1 billion for acute care and JPY3.9 billion for overseas. As a result, consolidated net sales will be JPY49.0 billion.

One point I would like to make here is that in the fiscal year ending September 2023, women's healthcare accounted for 44% of our Company's total, and this year that figure will increase further to over 48%. We believe that our Company's presence in this field is increasing more and more.

I have just spoken mainly about the area of women, but if we compare this with the final year of the medium-term management plan announced 4 years ago, you will see the following results.

Although the breakdown differs slightly from the plan at that time, we plan to achieve approximately the same consolidated net sales and operating income as a result of significant growth in the women's healthcare field. The amount was JPY10.8 billion 4 years ago, which I will explain on the next slide, and I said that we would double the amount to JPY20 billion by the final year, mainly in the area of women's healthcare. We have prepared a new product portfolio over the past 4 years, and although there was a slight delay, the supply system in Toyama is now in place. We are planning JPY23.7 billion in the women's healthcare field for the current fiscal year.

The key to the quantitative aspect of our business plan for this fiscal year depends on whether or not we can deliver drugs to patients in the women's healthcare field. I would like to explain a little more about that point compared to when the medium-term plan was announced.

The upper row shows the actual and planned values for the 6 main products, which we have been using since the announcement of the medium-term management plan.

We said that we would double our sales from JPY10 billion in the September 2020 fiscal year to JPY20 billion by the final year of the medium-term management plan 4 years ago. As for the breakdown at that time, the "Others" section at the bottom of the chart remained unchanged, while the JPY5 billion for the 6 main products was doubled to JPY10 billion. I mentioned that new products, which did not exist at the time, would amount to JPY5 billion, which would add up to JPY20 billion as a whole. As for our 6 main products, a new

plant in Toyama was launched in the previous fiscal year, and we expect growth in oral contraceptives in the future.

In addition, new products such as F-meno capsules, estradiol, and Doxil in the bottom row, which were not available 4 years ago, have been delivered to the medical field and patients, and quantitative results were already obtained in the previous fiscal year, totaling JPY [inaudible] billion for the 2 products.

This fiscal year, by promoting the measures I mentioned earlier, we will make solid growth this fiscal year, focusing on this women's healthcare area. This is our plan for the current fiscal year.

Next, I would like to talk about our new products and our overseas business plans for this fiscal year.

Here is the pipeline for new product development.

We have been presenting these separately, but now we have included biosimilars as well. Our pipeline consists of 3 major categories: drugs for dysmenorrhea, drugs for menopausal disorders, and biosimilars.

I will now explain each of the 3 products, and Naganawa, Executive Officer, Deputy General Manager of R&D Division, will explain our developing products, 013 and PH-80. If you have any questions about the market, I would like to provide a separate explanation in the Q&A session.

Now, Naganawa will explain about FSN-013, which we expect to be our next product to support the women's healthcare field.

Naganawa: I am Naganawa, from Research and Development Division. I would like to explain the new progress on FSN-013.

We have been developing this drug as a next-generation treatment for dysmenorrhea and have completed the analysis of data, and in October this year we filed an application for the indication of dysmenorrhea. We will now proceed with the review process with the authorities.

In addition, interesting results were obtained regarding the blood coagulation system of estetrol, which is one of the characteristics, and will be explained in the next slide today.

This graph shows D-dimer trends and the frequency of exceeding the upper limit when FSN-013 or placebo is administered to patients with organic dysmenorrhea, functional dysmenorrhea, and endometriosis.

D-dimer, primarily venous thromboembolism (VTE), has clinical utility in the evaluation of patients with suspected deep vein thrombosis and pulmonary embolism. As for the figure, the right-hand side shows the D-dimer trend, and the left-hand side shows the frequency of D-dimer exceeding the upper limit of the reference value.

The figure on the right shows the transition from Cycle -1 before administration to Cycle 6. As for a Cycle, 1 Cycle is counted as 28 days, which makes a total of 24 weeks, and data is taken for each of them. This is shown here as mean and standard deviation. The red line above shows the reference value.

The results of FSN-013, the dark blue line, show that the values were within the reference values even before administration and that the values remained flat or showed no change. The light blue line shows the placebo group, which also showed no change from the pre-administration period.

The results of FSN-013 and placebo show a similar level of transition, indicating that there is little effect of the drug.

The figure on the left shows the results of the analysis of the percentage that exceeded the upper limit of 1 μg/mL. The FSN-013 result was 5.0 vs. 8.4 for placebo, indicating that the FSN-013 result was lower than the placebo result.

There was also little effect on other blood coagulation markers, suggesting that the drug has little effect on the blood coagulation system.

The follicle hormone used in conventional dysmenorrhea medications, mainly ethinyl estradiol, is expected to reduce the side effects of thrombosis, which is often reported with combination drugs containing this hormone.

That is all I have to say about FSN-013.

Iwai: Next, I would like to talk about the dysmenorrhea market, where we will be introducing FSN-013, and our capabilities in this market.

This is the overall picture, and women are advancing more and more into the workforce. In addition, the diversification of lifestyles and interest in health are also increasing. The left graph shows the overall market for dysmenorrhea treatments, which has been expanding significantly.

In 2015, it was JPY18.3 billion, and by 2022, it will more than double to JPY41.5 billion. We are planning to launch 013 in this market: we have already had a track record since 2008 in this market. In 2008, we began co-marketing a product called Lunabell, Nobelpharma's dysmenorrhea treatment, which is also sold by us.

Peak sales of Lunabell, our product of the same name, were approximately JPY4 billion, and this is only for our Company. Since then, generic versions of Lunabell have been sold by other companies, and our sales of Lunabell have declined significantly.

However, by taking advantage of our experience in the market through the sales of Lunabell for dysmenorrhea treatment and its track record, as well as the characteristics of the product, such as the low effect on the blood coagulation system as mentioned by Naganawa, we will make FSN-013 the next top product in our lineup. This is becoming an important issue to be addressed in the next fiscal year and beyond.

This is an overview of 013 products and the market.

Next, I would like to talk about menopause drugs.

First, I would like to discuss our Company's approach. We are already marketing follicle hormones such as L' estrogel and Estradiol tablets in this field of hormone replacement therapy, as described here. The progesterone used at the same time as the follicular hormone, the other progesterone is F-meno capsules, which I have already explained and have been delivered to patients since 2021.

On slide 11, I mentioned that the market for drugs for menopausal disorders is currently limited, but on the previous slide, I mentioned that the market for drugs for dysmenorrhea has been growing significantly over the past 10 years. As the use of hormone preparations used in the dysmenorrhea market expands, the market for hormone replacement therapy in the treatment of menopausal disorders will also expand over time.

On the other hand, as described in the upper part of this slide, symptoms during menopause are diverse, and there are patients with various problems. We will offer a wide range of products that can solve many of these problems, and not just hormone preparations. We believe this is our mission.

Currently, a new hormone replacement therapy drug using a new follicle hormone called E4, which has the same ingredients as FSN-013, has completed Phase 1, and we are currently discussing the future development policy. In addition to these hormone preparations in the upper part of this slide, we are also developing non-hormone preparations and medical supplements.

Today, Naganawa would like to give an overview of PH80, a non-hormone product for which we concluded an exclusive negotiation agreement with a U.S. company, Vistagen, in September this year.

Naganawa: I will now give an overview of the new therapeutic agent, PH80.

This is a nasal spray product being developed by a U.S. company called Vistagen Therapeutics. In September 2023, the Company acquired the agreement on exclusive negotiating rights for the development and commercialization of the product in Japan.

The drug is thought to have a therapeutic effect on vasomotor symptoms associated with menopause, the so-called hot flashes, by activating chemical neurons in the nasal cavity.

In the Phase 2 study with 36 cases, a double-blind, placebo-controlled study, hot flashes were significantly reduced within 1 week of administration. The results show that they have been able to maintain this since then. They also reported a significant reduction in the severity of hot flashes or dysfunction and sweating during the treatment period. On the safety side, there were no serious adverse events, and the adverse event profile was comparable between PH80 and placebo, indicating that the drug is well tolerated.

In the U.S., we will be developing the product in the future. Our company will examine the data from PH80 and here, and will proceed with the consideration of development in Japan. We would like to explain again as soon as progress is made. That is all from me.

Iwai: In this market for drugs to treat menopausal disorders, we believe that this is a market that we should pay more attention to in the future.

While we expect the use of hormone replacement therapy to increase in the future, we also believe that it is important for us to provide a variety of treatment options, and we will continue to work hard to address this market from both perspectives.

Finally, I would like to conclude my overview of this fiscal year's plan by mentioning biosimilars and overseas business.

This slide shows the development pipeline for biosimilars, which has been shown in the past.

We have concluded a development agreement with Alvotech of Iceland for 7 products for the Japanese market, and are currently in the process of developing these products.

It has been a long time since I started showing you this slide, but what has materialized since then is the fact that we obtained approval for ustekinumab in September this year, as I mentioned at the beginning of this presentation.

In addition, we are currently working with Alvotech on a plan to submit an application for approval of the next 3 products during this fiscal year. In order to ensure the delivery of these products to patients, having a new area a bit, we have established a new organization dedicated to this new area and a medical affairs division in October, and are building an effective information provision system.

As for our future sales target in the biosimilars area, we have no revision about our sales target from JPY15 billion in 2029 at this time.

Next, then, I'll talk about overseas.

I would like to divide my explanation broadly into ASEAN and the United States. In the ASEAN region, as I mentioned in September 2023, we will focus on Nextstellis, which we began full-scale sales in April 2023, as the core of our portfolio, and increase the number of surrounding products. In addition, we would like to focus on the production and marketing of OLIC, while expanding our CMO business.

As for the U.S. market, as I have already mentioned, OLIC and Fuji Pharma are currently working on respective concrete plans for the U.S. market, and we will focus on further materializing these plans and steadily starting to supply products during the current fiscal year ending September 2024.

We will proceed with the development in ASEAN in the Asia region, access to the U.S. market, and access to the U.S. market with caution. We are determined to do these things well this fiscal year.

In closing, I would like to say a few words as a summary.

Thank you for your attention. This is a summary of what I have said so far. In this context, I believe that the key to achieving the business plan for the current fiscal year is pretty much concentrated on how to reliably deliver pharmaceuticals needed in the area of women's healthcare to patients, and we will steadily take steps in this area.

In the next fiscal year and beyond, we will also work to secure approval for FSN-013, which we expect to be our next top product, in order to further help patients. Then, new biosimilar applications for approval. Then, we get approval for generic products that support our core products. We would like to focus on these things domestically, and then expand our overseas operations, as I mentioned earlier, to ASEAN, the U.S., and other overseas areas like these.

As I explained today, we have grown as a generic company in the past, but this fiscal year, we will further advance our efforts to become a specialized pharmaceutical company by specializing in even more specialized fields [inaudible].

I would like to conclude my explanation by mentioning our dividend policy.

The Company's dividend policy is to maintain a dividend payout ratio of 30%, based on stable dividends. For the current fiscal year ending September 30, 2024, we plan to pay an annual dividend of JPY42.50 per share, applying a dividend payout ratio of 30%, excluding extraordinary factors.

With that, I will conclude my explanation. Thank you very much for your attention.

Moderator: Thank you for your explanation.

Question & Answer

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

If you have any questions, please enter them in the comments section on the screen.

Information on how to send chats. If you are viewing the video from a computer or other device, there is an area below the video where you can enter your message. After entering the information here and pressing the submit button, the information you have entered will be displayed and the submission will be completed.

If you are viewing this from a smartphone, please scroll down the screen to display the input area. The method of transmission, etc., is the same. We look forward to receiving your messages.

Thank you for all your questions. The first question.

The first one is here.

Questioner [Q]: Is the new formulation building already in operation? Please tell me about this. We received these questions.

Iwai [M]: Thank you. Morita will explain and answer the question.

Morita [A]: Let me answer the question. The new formulation building was planned to manufacture hormonal tablets, mainly oral contraceptives. As for the current situation, we have obtained all the necessary permits for the manufacturing facilities and the manufacturing building, and manufacturing has been completed.

We are currently checking the quality of the manufactured products and plan to ship them as soon as they are confirmed. That is all.

Moderator [M]: Thank you. Now for the next question. This is here.

Questioner [Q]: I heard that you are going to start trial sales of emergency contraceptives. Are your company's preparations for and responses to the test marketing and OTC marketing underway?

Now, please answer the question.

Iwai [A]: Thank you for your question. The news has just now been appearing in the industrial papers and also in the general press. As for the current situation and our response, Morita, Head of Corporate Planning will explain and answer the question.

Morita [A]: As Iwai just mentioned, last Friday, the 17th, the Ministry of Health, Labor and Welfare announced that trial sales of this emergency contraceptive, which can be prescribed without a doctor's prescription, will begin on the 28th of this month at pharmacies.

We are not in a position to give an answer on the future direction, so we will refrain from doing so, but regardless of the direction after trial sales, we will closely monitor the situation and prepare our manufacturing and sales system so that we can fulfill our responsibility to supply the product. That is all.

Moderator [M]: Thank you. Now for the next question. This is here.

Questioner [Q]: Why did you apply for FSN-013 only for dysmenorrhea? You don't apply for endometriotic pain? Also, what would be the impact of not applying for it?

Now, please answer this question.

Iwai [A]: Regarding your question about the application for 013 indications, this is currently under consideration by the R&D department, so Naganawa will explain it.

Naganawa [A]: We are currently analyzing the results of the clinical trial for endometriotic pain. After that, we are also considering moving toward the application process. With regard to E4, we believe that it has various potentials, and we will continue our efforts to maximize the value of the product.

Moderator [M]: Thank you. Now for the next question. This is here.

Questioner [Q]: What was the reason for not listing ustekinumab on the drug price list? Please let me know. We received this question.

Iwai [A]: I would like to explain this one.

The reason for not listing the drug on the drug price list this time is that we are currently in the process of confirming the production plan of the overseas manufacturing plant again. Therefore, we have decided to delay the drug price listing for the time being and actually delayed it, after confirming that we have a sufficient amount of inventory to ensure a stable supply and that the product can be launched and sold without any problems.

However, this does not mean that there was something wrong with the production, and the production itself is proceeding smoothly. I hope you understand that this is a production planning issue.

On the other hand, as supplementary information, I mentioned that we are planning to apply for approval of 3 additional formulations this year, and I wonder you may have a question if there will be any impact on these applications by that delay.

The development of these 3 products has been delayed slightly due to the impact of Covid-19 and other factors, especially entries of patients at overseas studies, but the development itself is generally progressing as planned. In any case, we would like to develop the product and establish a supply system with a stable supply in mind. That's all.

Moderator [M]: Thank you. We are currently sorting out the questions status. We would like to ask you to wait for a while as it is. If you are preparing your question now, please let us know you have a question first, and then send us the content of your question.

Our staff is waiting for you and would appreciate your cooperation.

Thank you for waiting. Now for the next question. This is here.

Questioner [Q]: On the Biosimilars Development Progress page, why have the arrow lengths changed for B and C from the previous disclosure documents? We received this question.

Iwai [M]: Regarding the next scheduled development, Naganawa would like to give a more detailed explanation of the status of this development.

Naganawa [A]: Let me answer the question. The length of the arrow indicates that there has been a slight delay in development due to the impact of Covid-19 and global logistics, especially in clinical trials. This shows a slight delay in the development of the product.

Moderator [M]: Thank you. Now for the next question. This is here.

Questioner [Q]: The proposed elimination of initial clinical trials for Japanese, can we see this as a positive for your Company's performance? How about this question?

Iwai [A]: Thank you for your question. We and our Company are looking at this article with great interest. As to whether or not this will be a positive factor for our future R&D, I would like to ask Naganawa, who is the Deputy General Manager of R&D Division, to add a few words.

Naganawa [A]: Let me answer the question. In clinical trials, there are development guidelines for each disease, and it is difficult at this point to determine whether or not the proposed abolition of early clinical trials will have a positive effect.

We will consult with the authorities on the development of each individual development project, to proceed with the development. Of course, we would like to make every effort to provide pharmaceutical products to patients as soon as possible.

Moderator [M]: Thank you. As the end of the session is approaching, we would like to conclude the Q&A session.

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 everyone for a favor. Please send us your opinions and impressions of today's web-based financial results presentation by filling out the questionnaire. The survey is located at the bottom of the screen under the Explainers, Slash, and Resources tabs. The survey can be viewed by clicking here portion. The questionnaire will be distributed via e-mail after the briefing as well. I appreciate your cooperation.

This concludes the presentation of the financial results for the fiscal year ending September 30, 2023, of Fuji Pharma Co., Ltd.

Thank you very much for your participation 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].*
3. *Speaker speech is classified based on whether it [Q] asks a question to the Company, [A] provides an answer from the Company, or [M] neither asks nor answers a question.*
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