Presentation

Okatake: Good morning, everyone. Thank you for taking time out of your busy schedule today to participate in the presentation of the consolidated financial results of Fuji Pharma Co., Ltd. for the fiscal year ending September 30, 2025. My name is Okatake from Fuji Pharma and I will be your moderator. Thank you very much for your cooperation.

The presentation materials for the fiscal year ending September 30, 2025 financial results briefing have been posted on our website today. Please have them ready at hand or view the materials we will project.

Let me now introduce the attendees. Shuhei Morita, President and CEO. Atsuya Mitsuhashi, Executive Corporate Officer, Corporate Planning Department, Corporate Strategy Division. Hiroshi Uji, Corporate Officer, General Manager, Corporate Business Management Department.

First, Morita will give a 30-minute presentation, followed by a Q&A session. Questions can be submitted via voice and text. For text questions, click on Q&A at the bottom of the Zoom screen to enter and submit your question. Please note that any questions sent during the meeting will be answered after the presentation.

We will now begin our explanation.

Morita: I am Morita from Fuji Pharma. Good morning, everyone. Thank you very much for taking time out of your busy schedule today to participate in the financial results briefing for the fiscal year ending September 30, 2025 of Fuji Pharma Co., Ltd.

Let me begin with an explanation.

Here is the summary. In the fiscal year ending September 30, 2025, net sales and operating profit both grew by double digits. Operating profit increased by 27.9%, driven by expanded sales of new products and an improved gross profit margin due to a better product mix. The Company has adopted a progressive dividend policy and plans to pay a dividend of JPY45.5 per share for the fiscal year ending September 30, 2025.

The first year of the Mid-Term Business plan got off to a good start. Both sales and operating profit reached record highs, thanks to contributions from women's healthcare, biosimilars, and other products.

In the fiscal year ending September 30, 2026, we expect continued expansion in women's healthcare, biosimilars, and global CMO.

In addition, Alyssa, a new dysmenorrhea drug launched last December, has steadily gained strength over the past year, and we plan to further expand its sales, starting with the lifting of prescription restrictions from this December onward. We are also moving forward with preparations for the NHI drug price listing and launch of 3 biosimilars approved in September of this year.

Here is today's agenda. I will give an overview of the consolidated financial results for the fiscal year ending September 30, 2025, the consolidated forecast for the fiscal year ending September 30, 2026, and the key business topics, and then I will be happy to accept Q&A sessions. Thank you very much.

First, a summary of consolidated financial results for the fiscal year ending September 30, 2025. Net sales totaled JPY51,677 million, up JPY5,538 million, or 12%. Gross profit was also up 16.4% to JPY20,763 million. Operating profit was JPY4,990 million, an increase of JPY1.11 billion, or 28.6%, with double-digit growth in both net sales and operating profit.

Earnings per share, which is the KPI for this mid-term plan period, was JPY141.87, an increase of 28.1%. And ROE improved significantly with the increase in operating profit.

Next, I will explain the results by business segment. In women's healthcare, sales were JPY22,372 million, up 7.7%. Biosimilars business increased by 7.4% to JPY1,973 million. The CMO business recorded JPY8,342 million, a 4.9% increase. All 3 growth strategies outlined in this Mid-Term Business plan, women's healthcare, biosimilars, and global CMO, are showing growth.

In the Others category, the amount of JPY18,989 million, or 25% of the total, was a significant increase. This includes 3 generic products launched in the fiscal year ending September 30, 2024, products inherited from other companies, and sales license income from future consignment sales.

The following are sales figures for our main products for the fiscal year ending September 30, 2025. First of all, F-meno Capsules for women's medicine, which is a hormone drug used to treat menopause in women, was a very hot topic at the most recent meeting of the Society of Women's Medicine. There is a major move to do something to solve the current issue that awareness of the disease is still low, the consultation rate is low, and hormone therapy is not being provided. As a result, sales increased to JPY4,311 million, or 35.5%.

Under F-memo, the sales of UTROGESTAN, Favoir, DOXIL, and Labellefille remained steady. With regard to Alyssa Combination Tablets, which were launched in December, we had planned for JPY1.1 billion in the first year of its launch, but the actual result was JPY512 million, far short of JPY1.1 billion we had planned. We will explain this in more detail later.

As for biosimilars, Filgrastim biosimilar, launched in 2013, slightly declined due to the NHI price revision, but USTEKINUMAB biosimilar, launched last year, has gradually penetrated the market, resulting in positive results for biosimilars. Other is as shown.

We have also presented the factors for changes in net sales and operating profit for the fiscal year ending September 30, 2025, in the form of YoY changes and changes from the initial forecast.

Net sales increased from JPY46,138 million in the previous year to JPY51,677 million, with JPY1.2 billion in women's healthcare and a small increase in biosimilars and CMOs. As I explained earlier, the sales in the Other segment have increased significantly to JPY3.8 billion.

On the other hand, compared to the initial forecast of JPY53,360 million, we were able to achieve higher sales than planned in the Other segment , but fell slightly short in CMO and BS, and in women's healthcare, as I mentioned earlier, we fell short of the plan, especially for Alyssa, resulting in a total of JPY51,677 million.

Operating profit increased by JPY1,100 million from JPY3,880 million in the previous year to JPY4,989 million. The main reason for the increase was an approximately JPY2,900 million increase in gross profit, which was accompanied by a corresponding increase in SG&A expenses, resulting in a net increase of JPY1,100 million.

Compared to the initial forecast of jpy4,850 million, the positive factors of lower than planned R&D and SG&A expenses were offset by the lack of sales, resulting in a gross profit of JPY4,989 million.

I would like to continue by explaining our consolidated forecast for the fiscal year ending September 30, 2026. Net sales are expected to increase by 11.2% to JPY57,490 million. Gross profit is expected to be JPY23,690 million, or 14.1%, and operating profit JPY5,520 million, or 10.6%. For the fiscal year ending September 2026, we anticipate double-digit growth in both sales and operating profit, continuing the trend from the previous fiscal year.

Earnings per share will be JPY156.60, an increase of 10.4%. ROE is also expected to continue to improve.

The next section is forecast by business segment. In women's health care, the amount is expected to be JPY25,280 million, an increase of 13%. As for biosimilars, 3 products finally approved this September will start making quantitative contributions, resulting in an 88.5% increase to JPY3,720 million. And CMOs will remain steady at JPY8,500 million, an increase of 1.9%.

This is followed by the sales forecast of key products. As I mentioned at the beginning, the market penetration and market expansion of F-meno Capsules is still continuing, and our full-year forecast for the fiscal year ending September 30, 2026 is JPY5,100 million. As for Alyssa Combination Tablets, the initial year's sales did not reach the plan by much, at JPY512 million, but we are now forecasting JPY3,100 million, starting with long-term prescriptions that will be available from this December.

As for biosimilars, we expect JPY600 million from further penetration of USTEKINUMAB, and 3 biosimilars approved in September are expected to make a combined quantitative contribution of JPY1,500 million. The Others segment is as shown.

Dividends. The Company plans to pay JPY45.5 for the fiscal year ending September 30, 2025. For the fiscal year ending September 30, 2026, we plan to pay JPY47 per share in accordance with our shareholder return policy.

From here, I would like to talk about the key business topics. This is our long-term vision 2035, which we disclosed a year ago, and the growth strategy of our Mid-Term Business plan for the preceding 5 years to realize it. Today I will share topics from women's healthcare and biosimilars in this growth strategy.

In the segment of women's health care, the first product to introduce is the Alyssa Combination Tablet. For the fiscal year ending September 30, 2026, we are determined to achieve sales of JPY3.1 billion. On the other hand, we did not reach our first-year plan. To look back briefly, there were high expectations for reducing the side effects of thrombosis, and the ingredient estetrol contained in Alyssa was highly anticipated because it is thought to be less likely to cause so-called thrombosis.

To explain what happened as a result: since thrombosis is said to occur more frequently in older age groups, particularly those in their 40s and beyond, there was an expectation that this drug could be used for high-risk groups prone to thrombosis, specifically older individuals. Consequently, prescribing was heavily skewed toward this demographic during the initial launch period.

As time went on, more doctors began prescribing it, allowing patients to experience its effects. However, among these cases, not limited to thrombosis but including minor issues like headaches and nausea, as noted here, a certain number of patients experience headaches or nausea within the first month, 2 months, or 3 months of starting this LEP formulation, making it difficult for them to continue the medication. The doctors have evaluated the product as a good choice for such patients, and they are now starting to prescribe it to a wide range of age groups, mainly to new patients.

The graph on the lower left shows the results of Alyssa Combination Tablets by quarter. We have received large-scale inventory placements from medical institutions and authorized dealers. Subsequently, inventory remained stubbornly high through the second and third quarters, and with prescriptions themselves not increasing significantly, performance stagnated; however, entering this fourth quarter, inventory cleared, and new prescriptions commenced across a broad age range, primarily among new patients. This enabled us to achieve results of JPY220 million.

If you turn to the graph on the right, here are the results of the survey. The survey was conducted in July 2025 with the cooperation of more than 300 obstetricians and gynecologists. The survey asked how many patients would be able to receive Alyssa when the long-term prescription ban is lifted in December, taking the number of patients who were prescribed Alyssa in July as 1.

Responses were about 5 times more likely to result in a prescription for the patient. Simply multiplying the current JPY220 million by 5 would yield sales of nearly JPY4,000 million; however, considering various factors, we have set our plan to first reliably achieve JPY3,100 million.

And then we will continue with information about the Conference. FIGO is the International Federation of Gynecology and Obstetrics, the world's largest international conference, with 146 countries and regions represented and more than 5,000 participants. This year's conference was held in South Africa in October, and we have a video message from Dr. Yutaka Osuga, Professor Emeritus of the University of Tokyo and Professor and Director of Teikyo University Clinical Research Center, regarding the conference report.

Video: Hello everyone. I am Osuga of Teikyo University. First of all, I would like to talk a little about the review of Alyssa Combination Tablets, which were launched by Fuji Pharma last December.

This Alyssa is a drug used to treat dysmenorrhea and is a low-dose estrogen-progestin combination called LEP. A unique feature of this product is that it is the first in Japan to contain E4, an EE-type estrogen from estetrol.

Estetrol E4 is a natural type of estrogen made in the fetal liver and differs in its action characteristics from the synthetic estrogen ethinylestradiol EE, represented by the existing LEP.

A serious side effect of estrogen-containing preparations is increased blood clotting, but estetrol E4 is of particular interest because it may have less risk of blood clotting. In other words, it is expected to be safe.

Alyssa Combination Tablets are approved in Japan for the treatment of dysmenorrhea, but are marketed overseas as an oral contraceptive. I recently chaired a session at FIGO, the world's largest obstetrics and gynecology conference, held in South Africa in October to showcase the value of natural estrogens in birth control pills. Today I would like to share with you some of the recommendations made at the FIGO session.

This picture shows the presentation at FIGO, I am second from the left. Pictured here are members of a project called ESCONEC, which consists of experts from around the world. I have been working with them for about a year to evaluate estrogen in birth control pills, compiling the results into a white paper and presenting it as a recommendation at FIGO.

First, let me explain the ingredients contained in birth control pills. Birth control pills are available as either a combination of estrogen and progestin or progestin alone. The ESCONEC project white paper also discusses the implications of including estrogen in birth control pills.

Estrogen is one of the female hormones and acts on various tissues of the body. Therefore, when birth control pills contain estrogen, one can expect good side effects in addition to contraception.

For example, unexpected bleeding is a concern for women who use birth control pills, and many stop taking them because of this. Estrogen is thought to prevent unexpected bleeding and has the benefit of making it easier to continue taking the drug, so in this regard, it is stated that a drug containing estrogen and progestin is preferable.

Currently, the estrogens contained in birth control pills sold around the world include synthetic ethinylestradiol EE, natural estradiol E2, and estetrol E4. The white paper states that the natural form of estrogen in birth control pills is preferable because it is easier to use and better tolerated by women who are sensitive to hormonal side effects due to its low thrombosis risk, desirable effects on blood vessels, bones, and lipids, and low liver effects.

I would like to mention one of the characteristics of natural estrogen-containing preparations: safety. The graph on the left shows the risk ratios for venous thromboembolism, VTE, from the European side effect database.

The vertical axis arranges contraceptives containing synthetic estrogens in the upper row and natural estrogens in the lower row. The more the graph extends to the right, the more thrombosis-related side effects are reported. On the other hand, the leftward extension indicates a lower number of reported thromboses, and natural estrogen-containing products have a lower incidence of venous thromboembolism.

See the graph on the right. Looking at past data in Japan, there was a period when there was a string of deaths due to venous thromboembolism caused by taking LEP. During the period when the Safety Bulletin, or Blue Letter, was issued in January 2014, the number of people taking the drug declined due to safety concerns. For this reason, it is extremely important to use drugs with a higher level of safety.

The recommendations state the hope for E4 among natural estrogens, that E4 is suitable for women who are sensitive to the side effects of hormones, and that it may be a safer option with respect to breast cancer risk.

Next, as a feature related to the efficacy of natural estrogen-containing preparations, their effect on pain associated with endometriosis has also been noted. The figure you see compares the impact of 5 different types of low-dose oral contraceptives and a single dienogest-dienogest on pain associated with endometriosis.

The white paper states that natural estrogen-containing preparations may be more effective in improving pain than synthetic estrogen-containing preparations. Furthermore, among natural estrogen-containing preparations, those containing E4 have been shown to exhibit similar efficacy to dienogest monotherapy for endometriosis and may be more effective against pain than synthetic estrogens.

Although we were only able to present a portion of the contents of the white paper, the inclusion of natural estrogens in birth control pills is desirable from the standpoints of safety, efficacy, and tolerability, and there are high hopes for further worldwide use of these products in the future.

The recommendations I would like to present here are a major step forward to lead to future revisions of practice guidelines in countries around the world. In Finland, prior to this recommendations, contraceptive guidelines were revised this past January. The fact that preparations containing natural estrogen already state they carry a lower risk of thrombosis and fewer adverse effects on health and the environment compared to preparations containing synthetic estrogen became a major topic of discussion within the conference.

We believe that the importance of estrogen in contraceptives and the differences between natural and synthetic forms of estrogen will be discussed in detail in countries around the world, leading to the revision of medical guidelines. Since estrogen-containing contraceptives are desirable in Japan for women who do not wish to become pregnant, and natural estrogen is preferable to synthetic estrogen, we believe that Alyssa, a drug containing significant natural estrogen, could be the first choice for dysmenorrhea treatment.

Today, I introduced the global trend of natural estrogens and the expectations for Alyssa Combination Tablets in Japan. I hope this message will help to deepen your interest in and understanding of women's healthcare.

Morita: Just now, Dr. Osuga talked about the significance of containing estrogen, which is a female hormone, and the benefits of natural estrogen.

This chart shows the domestic market for estrogen- and progestin-containing preparations, known as LEP preparations. They are growing significantly from 2019 to 2024, with an average annual growth rate of 18.3%.

We have listed ingredients A, B, and C as components, but until Alyssa was launched, the market consisted of 3 components, all of which are synthetic estrogens. Incidentally, its market size is JPY58 billion in terms of NHI price for Alyssa as of 2024. With Alyssa, the only product containing natural estrogen E4 in this market, we aim to achieve sales of JPY10 billion as soon as possible and contribute to doctors and patients.

I will continue to share topics on biosimilars. Regarding biosimilars, particularly the domestic biosimilar business, we often receive questions such as whether the business is financially viable or whether it is difficult to predict the business outlook.

Once again, I would like to introduce the biosimilars business in Japan and how we can make it successful, as I have briefly organized it. Currently, there are 18 biosimilars available in Japan. Six of these are sold independently, so there is no competition. And for the 12 ingredients, there is competition, with multiple companies participating.

Naturally, when switching to standalone sales, the volume and revenue from the transition from the previous product will directly impact the figures. On the other hand, when there are multiple companies, it becomes a battle for market share, and this is when the market share moves significantly.

If you look to the right, you'll see that when multiple biosimilars are launched, the key point is this: within the biosimilar market share, the product that launches first will always hold the top share. Conversely, if we are the first to market the product, we can contribute at least 50% to 70% or 80% of the market volume and sales.

Currently, all 5 ingredients for which we hold approval are either stand-alone or first on the market. We intend to make good use of this advantage to increase sales.

Also, regarding this point indicated by the arrow, currently, among these 18 ingredients, only 4 have achieved over 80% substitution with biosimilars. It is only 22% of the total ingredients on the market. As you are all aware, to change this situation, the government last year set a target for fiscal year 2029 to decrease the proportion of these ingredients exceeding 80% to 60%. Incentives for medical institutions to switch to biosimilars have already begun.

With the advantage we have in the first place and the tailwind from the national policy, we will work to achieve our initial plan of JPY15 billion for the fiscal year ending September 30, 2029.

I have one more slide on biosimilars, and I would like to briefly introduce 5 ingredients that we have now.

Filgrastim, launched in 2013, is Biosimilar 1, and currently has the top market share of 75%.

Ustekinumab, which was launched last year, is also Biosimilar 1. Subsequently, we launched Biosimilar 2 and Biosimilar 3; however, our products account for 96% of the biosimilar adoption share in medical institutions, meaning we currently dominate the market. At this stage, the product accounts for 10% of the overall original prescription volume and is currently active solely for the dermatological indication of psoriasis; however, we anticipate significant future expansion into the gastroenterology field. Therefore, we plan to leverage the market share we have secured to drive this anticipated growth.

Next, regarding 3 ingredients approved in September 2025, first, for Golimumab, it is a standalone approval of Biosimilar 1. We are preparing for the NHI drug price listing and launch of the product in May, 2026, based on the contract with the manufacturer of the original product.

Then, Denosumab was approved as the sole approval of Biosimilar 1. We are preparing to list the drug on the NHI drug price list and launch the product by the end of 2026 under the same agreement with the manufacturer of the original product.

Finally, regarding Aflibercept, although it is listed as Biosimilar 2, as you know, it was independently added to the NHI drug price list on November 12th, the day before yesterday. Since this is an ophthalmology drug, we will promote it by consigning sales to Nitto Medic Co., Ltd. which is strong in the ophthalmology field, in order to maximize the value of the drug.

As you are already aware, on the same day this drug was listed in the NHI drug price list, the manufacturer of the prior product issued a press release stating that it had filed for a preliminary injunction related to the patent. In response, our Company also issued a press release yesterday. There is no problem with stable supply.

So far, I've been discussing the business itself, but this is the overall picture. The left-hand side shows the previous Medium-Term total and the right-hand side shows the current Medium-Term total, which is a bar graph of sales.

We forecast JPY51.6 billion in the first year of the Mid-Term plan, and JPY57.4 billion in the second year. And as you can see, the red bar represents the sales of women's healthcare, and the green bar represents biosimilars. Currently, it accounts for 46.7% of total sales, but we intend to increase this to 50.4% in the fiscal year ending September 30, 2026.

We believe that we have made a good start toward the goal of JPY80 billion in net sales while raising the composition ratio of highly profitable women's healthcare and biosimilars to 66%, as planned in the Medium-Term plan.

Finally, I would like to talk about the challenges facing Japan and our areas of focus. Due to the aging of the population, medical costs have skyrocketed. It is probably over JPY50 trillion at present. The Ministry of Economy, Trade and Industry (METI) reported last year that the total economic loss due to health issues specific to women is JPY3.4 trillion.

To address the major challenges facing Japan, our Company will contribute to optimizing healthcare costs and realizing a sustainable insurance system through biosimilars. In women's healthcare, we will further strengthen our commitment to these 2 key areas, aiming to resolve health issues specific to women and ultimately contribute to their well-being.

Finally, as we firmly pursue our Medium-Term management plan to achieve our long-term vision 2035, we would be grateful for your continued dialogue with us and for your guidance and encouragement.

This concludes the explanation. Thank you very much for your attention.

Okatake: That concludes the explanation from our side.

Question & Answer

Okatake [M]: Now I will take your questions. Please limit your questions to 2 at a time.

We will explain how to submit your inquiry. Questions can be submitted via voice and text. We will first accept your questions in audio, and then answer your questions in text. For voice questions, please press the raise your hand button on the screen. After that, the account of the person we have designated will be granted speaking privileges. A selection screen will appear on your computer. Please select “Unmute” and then proceed to speak. For text questions, please click on Q&A at the bottom of the Zoom screen, type your question, and submit.

We will now take your questions in voice. Please note that we will be calling you by your Zoom name, so there may be discrepancies with the exact pronunciation. We kindly ask for your understanding in this matter.

Now, Mizuho Securities, Ms. Ishida. Please go ahead.

Ishida [Q]: Thank you very much. I am Ishida of Mizuho Securities. Thank you for your explanation. I would like to make 2 points in my question.

First of all, regarding the R&D expenses in your forecast for the next fiscal year, I think that your company tends to have unmet R&D expenses throughout the year, but do you feel that there is a buffer against the forecast for the fiscal year ending September 2026? I would like to know your sense of that kind of image. This is the first point.

Morita [M]: Thank you for your question. Mitsuhashi, who is sitting beside me, will answer your question.

Mitsuhashi [A]: Thank you very much for your question. We have budgeted JPY4.6 billion for R&D expenses this fiscal year. This includes funds for the development of new biosimilars, the development of drug discovery infrastructure, and the acquisition of new drugs.

Whether there is a buffer. Although we have factored in a certain buffer, we intend to use this budget well in order to thicken our future development pipeline.

Ishida [Q]: Thank you. Secondly, regarding 2 biosimilar products from the previous period, I found it a bit peculiar that your Company entered into a partnership with the originator manufacturer, especially since your product isn't even an AG. Could you please explain 2 points: the advantages of partnering with the originator manufacturer, and how the profit impact differs compared to if your Company had sold the product independently?

Morita [M]: Thank you. Mitsuhashi would like to answer this question as well.

Mitsuhashi [A]: Regarding the press release we issued the other day, we are unable to provide a detailed answer. However, I would like to reply that the impact on business performance and profits is minor.

Based on this agreement, we believe that we have secured a stable supply, and we are moving forward with this agreement in a very positive manner. That is all.

Ishida [M]: Thank you.

Okatake [M]: Now, we move onto the next question. Tokai Tokyo Intelligence Lab, Mr. Yoshida, please.

Yoshida [Q]: Thank you. This is Yoshida, Tokai Tokyo Intelligence Lab. Thank you.

So, the first thing I would like to ask you about is Alyssa Combination Tablets. You anticipate significant sales growth this fiscal period, and I believe sales trends here will greatly impact the stock price. Looking at the slide on page 15, a survey of 330 physicians indicates a fivefold increase in prescription intent compared to July. If possible, I'd like to know the proportion of prescribing physicians within the overall physician population.

Additionally, I believe this is a very important point to include in the clinical practice guidelines. Could you first tell me what kind of timeline we should envision?

Morita [M]: Thank you for your question. I'm not sure I fully grasped the intent of your first question. Of the survey.

Yoshida [Q]: With 330 respondents, I was hoping to first understand what percentage of them expressed a willingness to prescribe.

Morita [A]: First, we conducted a survey of over 300 physicians, primarily targeting those who are already prescribing Alyssa.

For example, at that point, the number of patients prescribed by each clinic may vary—whether it's 1 patient, 3 patients, or 10 patients. But when long-term prescriptions are permitted, how many patients would a doctor who currently sees one patient be able to see? If you are seeing 10 patients now, how many would you increase?

When we add these figures together, looking at the far left of this bar graph, if we set the July figure as 1, the overall result shows a 5.3-fold increase. While we cannot disclose individual data points, we understand this indicates a very strong prescription intent.

I hope I have answered your question.

Yoshida [M]: I'm sorry, I don’t quite understand. So this is the same number of doctors for both July and December, at 330. So you are saying that the intention was to increase the number of patients in that context. Sorry, I misunderstood.

Morita [M]: No, there is a lack of explanation on our part, thank you for your question.

Yoshida [Q]: So what about guidelines?

Morita [M]: Regarding the guidelines, Mitsuhashi would like to answer.

Mitsuhashi [A]: As mentioned in Professor Osuga's comment, we have received a report from the academic conference that the guidelines were rewritten in Finland prior to the conference.

What moves will countries make to follow suit? Since this will be in the future, there are currently no guidelines in Japan or in Western countries that have been moved or decided upon.

Morita [A]: If I may add one more thing, I am aware that medical practice guidelines are led by academia and academic societies, and not something that pharmaceutical manufacturers are involved in. I am sure that the Japanese guideline will be developed based on the evaluation of evidence emerging in the global arena, as well as the trends in the U.S. and Europe.

These are the answers to your questions.

Yoshida [Q]: I understand. I don't know when the last time the guidelines were revised, but with the results of this FIGO, it is rather likely to be the first-line drug, isn't it?

Morita [A]: I am not in a position to give an answer as to how likely or unlikely it is, but I am hopeful that it will happen.

Yoshida [Q]: Thank you. I would also like to ask about the second point, about the warrants.

Last time, you canceled some warrants, but regarding whether further warrant cancellations are possible, what would need to happen for that to occur. I am sure this will also have an impact on your Company's stock price, but could you tell us what kind of financial strategy you are planning to implement as well?

Morita [M]: Thank you very much. Uji will answer your question.

Uji [A]: Uji answers your question. Currently, we have warrants, the second and third rounds. The second round, in particular, is currently priced at JPY2,000 per share. At present, we have sufficient funds on hand for working capital and immediate investments, so there are no particular issues; however, we are still actively exploring various options, including future pipeline opportunities.

We are still considering the timing of future investment and the amount to be procured, but now that we have a clearer picture, we are in the process of determining whether we need more funds or whether we can do it with our own funds, including borrowing at the front end.

It is difficult to say what we will do at this stage, but we are now considering what to do in light of future investments, etc., including the future pipeline.

Yoshida [Q]: In that case, as a supplement, you are currently operating in accordance with the Medium-Term Management plan, and if the investment schedule is later and the recovery of 3 biosimilar products, which are in the recovery period of the ones we are stocking this time, is brought forward to some extent, there is a possibility that you may cancel the plan. Is that correct?

Uji [A]: I will answer. Considering the timing of future funds becoming available and the cash inflows we expect to receive, we believe that if such a situation arises, cancellation may be possible.

Yoshida [M]: Thank you. That is all.

Okatake [M]: Now, we move onto the next question. Mr. Hashiguchi of Daiwa Securities, please.

Hashiguchi [Q]: I am Hashiguchi of Daiwa Securities. Thank you.

The first point is about Alyssa's plans for this fiscal year. According to the results of the questionnaire survey that you mentioned, the simple calculation shows that the total amount is JPY4 billion, but you said that you plan is JPY3.1 billion, taking into account various circumstances. Could you please elaborate a bit more on what factors were considered in these various situations?

According to the survey you mentioned, you said it was 5 times higher for those already prescribed medication; however, since you can only prescribe for 2 weeks at a time now, you haven't even prescribe it. If you can prescribe it for more than 2 weeks, I imagine some doctors might start prescribing it. What do you think?

Morita [M]: Thank you for your question. Mitsuhashi would like to respond to your question.

Mitsuhashi [A]: First, I would like to provide some additional information regarding the graph. Regarding the new patients shown in the middle section of this right-hand graph, when prescribing new medications for dysmenorrhea treatment, specifically LEP formulations, to patients visiting the clinic going forward, currently our drug is chosen only about some portion; however, the survey results from physicians, shown in the middle section, indicate a desire to prescribe approximately five times that amount, specifically, Alyssa Combination Tablets rather than other agents. New increases are also factored into this.

While some have suggested a simple calculation might indicate JPY4 billion, we understand that even with the lifting of restrictions on long-term prescriptions, most patients currently prescribed existing drugs or other medications with LEP still visit the clinic only once every 3 months. Therefore, switching from other medications may take some time for physicians considering such changes.

In addition to the results of this survey, we are also regularly conducting market research to determine doctors' prescribing intentions and how well they understand the characteristics of this formulation. We have based this sales plan on the results of those surveys.

In addition, since Fuji Pharma's sales plan has not been achieved for several fiscal years, we have been working on the overall budget again this fiscal year, as we do every year though, but this fiscal year, we have made our sales plan with even greater scrutiny.

Morita [A]: If I may add a little more, as to why the JPY4 billion became JPY3.1 billion, as Mitsuhashi just mentioned, this survey is about physicians' intention to prescribe. On the other hand, there is also the intention of the patient who receive the prescriptions, so we take that into consideration as well.

In fact, generic drugs have penetrated this market quite well. Switching from generic to Alyssa would still increase the price. The increase is about the same as a candy bar per day, or less than JPY30, so some facilities are switching over to the new drug, saying that it does not matter at all, while in other cases, patients are refusing to switch because the JPY30 per day is too much.

In this sense, we have set the amount at JPY3.1 billion, taking into account various factors, including the prescriptions of physicians and the actual conditions of patients. That is all.

Hashiguchi [Q]: I understand very well. Thank you very much. The second point is about your forecast for biosimilars for this fiscal year.

On page 11, you mention 3 products, Aflibercept, Golimumab, and Denosumab, and I am wondering if my understanding is correct that all 3 products are suggested to contribute to sales by September. In your explanation on page 21, you only mentioned that Denosumab are expected within 2026, but you didn't specifically talk about it, can we assume that it will be available by September?

Also, from the perspective of the size of the market for original products, JPY1.5 billion is quite small. Where does this factor lie?

Furthermore, while it's not uncommon for biosimilars from other companies to have such high demand that they're only available in limited quantities, I'd like to ask whether you have sufficient supply capacity in place should demand exceed this JPY1.5 billion figure.

Morita [M]: You asked 3 questions, first Mitsuhashi will answer the questions.

Mitsuhashi [A]: Thank you for your question. First, regarding 3 products on this page, JPY1.5 billion, I believe your question was whether all of them are based on the assumption to be launched.

Based on the agreement with the original product company, our disclosure regarding Denosumab is limited to stating that it will be within FY2026. At this time, we are unable to confirm whether Denosumab sales are included within this JPY1.5 billion figure. We apologize for this. This is the first point.

Second point.

Hashiguchi [Q]: Please explain the background behind this significantly smaller forecast compared to the initial market size.

Mitsuhashi [A]: First of all, there is a difference in drug prices between original products and biosimilars. Generally speaking, depending on the product and its ingredients, the drug price is often set at about half that of the original product. Our selling price is then calculated by applying a certain ratio to that base price, resulting in the final unit selling price.

From there, based on our analysis of the past and the market results, we are now in the process of making sales plans for the first, second, and third years. We have received suggestions that it may be a little small, but this plan is the result of various estimates.

You also asked whether a stable supply can be maintained in the event of higher-than-expected sales or demand. We are taking measures to ensure that there are no problems with stable supply by securing inventories in case sales or needs exceed the planned level.

Morita [A]: To add a bit more detail, regarding Aflibercept, as shown in the slide, our sales scheme does not involve direct sales to the market. I believe you can infer some aspects from that.

Regarding Golimumab, we are moving toward drug listing and launch in May. There are pre-filled syringes and auto-injectors markets for it, and our initial entry will be into the pre-filled syringe market, which is relatively smaller of the two markets.

I would like to add a little supplemental information. That is all.

Hashiguchi [M]: Thank you very much. That is all.

Okatake [M]: Don't you have any other questions? Then, we move onto the next question. Mr. Maeda of Nomura Securities, please.

Maeda [Q]: Thank you. I am Maeda of Nomura Securities. I apologize for asking such a detailed question, but on page 36, you discuss the menopause disorder market and the sales trends for menopause treatments. Recently, I believe a domestic patch manufacturer voluntarily recalled their patch formulations. I was wondering if the impact of this recall might have started showing around the fourth quarter of the fiscal year ending September 2025.

Have you already seen an impact on the actual results for that, and how are you incorporating this into your plans for the current fiscal year? I would like to ask you about it.

Morita [A]: Thank you for your question. As you just pointed out, voluntary recall took place in July, in the fourth quarter. Following this, it is true that we saw a surge in inquiries regarding switching to our products, such as F-meno, Estradiol Tablets, and l'estrogel, for patients who could no longer use their existing medications.

Since this was a voluntary recall of a product with a significant market share, we were not able to meet all of the demand, so we had to restrict shipments in the fourth quarters while we try all our best, which means that there was actually more demand.

We are still limiting the supply, but we have been working hard to increase production and deliver medicines to patients in accordance with the wishes of doctors.

Regarding this fiscal year's plan, we anticipate that demand will remain substantial if current levels persist. While we do not know a clear timeline for the resumption of shipments for the recalled product, we have formulated our plans based on the assumption that this could occur within a certain timeframe.

These are the answers to your questions.

Maeda [M]: I understand very well. That's all from me.

Okatake [M]: Now, we move onto the next question. Mr. Sakaguchi of Iyaku-Keizai-sha, please.

Sakaguchi [Q]: My name is Sakaguchi from Iyaku-Keizai-Sha. Thank you very much. Regarding Aflibercept BS, the original manufacturer has filed for an injunction against its manufacture and sale. Does your Company plan to take any legal action in response?

Morita [M]: Thank you for your question. Mitsuhashi will answer your question.

Mitsuhashi [A]: The reality is that the procedures have already begun. We respect this patent, and as we announced in a press release yesterday, we do not believe that this is patent infringement, and we intend to respond firmly and in good faith.

Sakaguchi [Q]: I understand. Other drugs, the same 2 biosimilars, are partnered with original drugs, but will you continue to explore such a direction?

Morita [M]: Thank you very much. We have received a petition for a preliminary injunction, and we are now in the process of responding to it, so we will first make a sincere effort to respond to the petition.

Regarding the earlier comment by Mitsuhashi, I would like to add that our Company was aware of this patent from the application stage and fully recognized its establishment, and we have proceeded accordingly up to the present.

Sakaguchi [Q]: Thank you very much. Just to confirm, when will Aflibercept BS be released?

Morita [A]: We are in the process of preparing for the launch, so we have not yet given the market a definite time frame, so I am sorry, but I would prefer not to discuss the launch date at this time.

Sakaguchi [M]: Okay, that's all. Thank you very much.

Okatake [M]: Does anyone have any other questions? Now we move onto another question. Tokai Tokyo Intelligence Lab, Mr. Yoshida, please.

Yoshida [Q]: Thank you. This is Yoshida, Tokai Tokyo Intelligence Lab. Sorry for the second time.

Regarding the menopausal disorder medication mentioned in response to Mr. Maeda's earlier question during the Q&A session, I'd like to confirm a few points about production capacity. I think they are made at OLIC in Thailand, but how are they handling the increased production? That is all.

Morita [A]: Thank you. As you mentioned, we are manufacturing soft capsules in Thailand, and we are already working together to increase production.

Yoshida [Q]: I think that is in the plan for this term, but if you expand further in the next term and beyond, have measures been taken to potentially increase production?

Morita [A]: We have production capacity. Production involves various processes, from making the capsules to inspecting and packaging them; however, one of those processes has become a bottleneck. By thoroughly addressing that bottleneck now, we aim to secure a system for increased production.

We hope you understand that we won't be overwhelmed when the market expands or sales increase.

Yoshida [M]: Thank you. That is all.

Okatake [M]: We are now accepting questions. Please feel free to ask any questions. With that, I will conclude the Q&A session.

This concludes the presentation of the consolidated financial results for the fiscal year ending September 30, 2025 of Fuji Pharma Co., Ltd. Thank you very much for attending today's session.

[END]

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