ASKA Pharmaceutical Holdings Co., Ltd.
2Q FY2024 Financial Results Meeting

QA Summary

November 12, 2024

Q&A Financial Results Meeting for 2Q FY2024

Q1: Please elaborate on the factors behind the increase in R&D expenses for this fiscal year. On the other hand, I would like to know why you have left the forecast for this fiscal year unchanged.

A1: Of 5.8 billion yen in the estimated R&D expenses for the current fiscal year, approximately 2.0 billion yen is related to exploratory research and drug discovery research, including personnel expenses, and the remainder is for clinical trials and other development-related expenses. In the second half of the current fiscal year, expenses are expected to increase due to progress in the development stage of AKP-022 and other drugs. Since we had originally budgeted for an increase in R&D expenses in comparison with the budget, we determined that there was no need to revise the plan for the fiscal year due to this increase.

Q2: I would like to ask about the product strategy for Relugolix combination tablets. Are you aiming to switch from existing treatments or to target new treatments? Which is your target, uterine fibroids or endometriosis?

A2: We expect that the Relugolix combination tablets will solve the problem of the limited duration of RELUMINA administration as a barrier in the pharmacological treatment of uterine fibroids. At the same time, we believe that the potential of the combination tablets can be expanded to patients who have not started pharmacological treatment. We recognize the potential for both.

In endometriosis, we are about to start clinical trials, but the concept is the same as for uterine fibroids. The first step will be to build a position among existing GnRH agents.

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Q3: I understand that you have introduced ion channel drug discovery technology, but I would like to know if the purpose is to strengthen ASKA Pharmaceutical's area of expertise or to develop a new field.

A3: Ion channel drug discovery has been addressed in the past as a project focusing on the three priority areas of internal medicine, obstetrics and gynecology, and urology. This time, ASKA Pharmaceutical will build a technological foundation for ion channel drug discovery on its own. In addition to the three priority areas, other areas will also be targeted. Ion channel drug discovery is an area where there are unmet medical needs, and we believe that we can contribute to this area.

Q4: What is the size of the LF111 market?

A4: LF111 is the first progesterone-only pill (oral contraceptive) in Japan. As shown on the slide, the market size in Japan is approximately 10 billion yen per year. Overseas, the market share of progesterone-only-pill is 10-20%, and we expect the same level in Japan.

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Q5: Regarding the collaboration with Hataphar in Vietnam, we heard at the last briefing that the start of commercial production at the new factory will be in 2027. I would like to know the background behind this acceleration to 2026; does this mean that the commercial production will reflect the PL of ASKA Pharmaceutical in 2026?

A5: We would like to start commercial production as soon as possible. We are currently preparing to obtain PIC/S GMP certification in 2025 and are also preparing to submit an application to the Vietnamese authorities. Based on a closer examination of the current situation, we have determined that we can start commercial production in 2026. The start of commercial production at the new plant will not directly affect our financial statements, but the performance of Hatafer as an affiliate accounted for by the equity method will be reflected in our financial statements.

Q6: When do you plan to enter the clinical stage of the pipeline AKP-017 and AKP-021?

A6: The timing is undisclosed. We aim to make progress during the period of Medium-Term Management Plan 2025.

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[Notes]

- Please note that the content of this material is a summary based on the purpose of the questions and answers.
- Forward-looking statements contained herein are based on our assumptions and beliefs in light of the information available to us as of the date of preparation and involve known and unknown risks and uncertainties.
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