

Q&A, the FY2008 Second Quarter Business Results Briefing

[Attendees]

Natsuki Hayama, President and Representative Director, Chief Executive Officer
Takeshi Komine, Representative Director and Executive Vice President
Michihiro Tsuchiya, Board Director, Executive Vice President
Kunihiro Shimojuku, Board Director, Executive Vice President
Ken-ichi Yanagisawa, Board Director, Managing Executive Officer
Junji Hamaoka, Board Director, Managing Executive Officer

[Business Results]

Q: Licensing-out contract fees, a factor in the downwards revision of the full-term forecast were ¥3.3 billion, ¥3.5 billion less than the initial forecast of ¥6.8 billion. Please describe the company's attitude on the budget calculations and the current licensing status.

A: There were projects that were quite certain at the time we disclosed the forecast in May this year. Because it was difficult to pinpoint timing in the subsequent negotiations, the figures this time have removed from the forecast. Now we are negotiating several projects and it is not the case that the negotiations have been unsuccessful. However, the fact that recent new drug reviews have been tightened up is also having a slight impact. We will be continuing with these negotiations.

Q: In regard to the forecast, there were many downward revisions for the products of the former Mitsubishi Pharma such as Radicut, Anplag and Urso. Were the target figures in the initial plan too high?

A: Certainly, we did not achieve the planned targets, but on an actual sales from wholesalers to end-users in quantity base, both Anplag and Urso definitely grew. We were planning to prepare new data for Anplag on arteriosclerosis obliterans and develop sales promotion activities in the first half of the year, but that has been delayed by about half a year. In regard to Urso too, the treatment guideline for hepatitis C (patients should be treated until reaching ALT30 or less) appeared in May, but the number of patients visiting hospitals for hepatitis treatment has not actually been as great as anticipated. The number of hepatitis C patients is said to be about 2

million, but the actual therapeutic objective is about 400,000. There is a potential market, but awareness has not penetrated the market to the extent we thought it would. We will continue to convey properly the significance of treatment on the guideline to medical profession and want to move closer to the planned figures.

Q: In Mr. Hayama's presentation, there was an explanation regarding the cerebral field that the sales forecast had been reduced due to the impact of the prospective payment system based on the DPC system, and the increase of DPC hospitals. What is the current situation - how do doctors use Radicut in DPC medical institutions?

A: We are struggling with promotion of Radicut. The biggest reason for that is the trend at DPC hospitals seeking to limit use of Radicut to the minimum necessary. The number of patients with cerebral infarction, the target of Radicut, is increasing, but the administration period per case has become shorter in comparison to before. As a company, we are increasing the number of specialized cerebral field MRs, and implementing promotion so that among sufferers of cerebral infarction, people with mild symptoms are also included for medical attention. In addition, it is also being explained that it is better to administer the drug for longer period against the tendency of the shortening of administration periods too. We think that it will be possible to expand the market when the impact of DPC comes full circle.

Q: Sales of Remicade have fallen from ¥8.9 billion in the 1st quarter to ¥8.8 billion in the 2nd quarter. There seems to be growth on a drug price base (page 5 of Mr. Hayama's presentation), but should we think that there was an impact from inventory adjustment as with other drugs? At present, what is the appropriate level of wholesaler inventory for Remicade?

A: I do not have the figures for Remicade alone, but at the end of the 1st quarter, wholesaler inventory for domestic ethical drugs overall was up ¥3 billion in comparison to the end of March and conversely, wholesaler inventory is being restrained at the end of the 2nd quarter so I think it is caused by that impact.

Q: The result for R&D expenses was ¥37.6 billion against a first-half plan for ¥39.5 billion. The forecast for R&D expenses for the full year has been revised to ¥74 billion against an initial forecast of ¥77.5 billion. In consideration with the non-budgeting of the payment to Cytochroma, is there a substantial non-spended

portion of R&D expenses? For example, have any development projects been delayed? Could you please explain the background?

A: One thing is that because the companies have only just come together, our respective divisions have not yet grasped a sufficient feeling for the level, organizationally, of the expenses they require for the execution of their work. Another thing is that cost synergy effects in R&D expenses are appearing at a speed in excess of the budget. Consequently, we are not aware that the progress of R&D processes has been delayed in particular.

Q: I have heard that the payment to Cytochroma was C\$105 million.

A: That figure of C\$105 million included investment in Cytochroma and milestone fees. Of that amount, as lump-sum payments in the first half of the year, the company posted a little less than ¥2 billion in R&D expenses and a share acquisition fee of ¥2 billion in investment securities.

Q: In the medium-term management plan, the annual target for R&D expenses in FY 2010 stands at ¥82 billion, but will this decrease to about ¥80 billion due to cost synergies?

A: New projects that were not envisaged in the initial budget have been added in R&D such as the in-licensing of CTA108 from Cytochroma and the joint development of Pazucross. In addition, due to factors such as the prospect that the company will use slightly more R&D expenses overseas too for other existing products, I can say nothing at this point in time about whether or not R&D expenses will fall below the planned figure of ¥82 billion in FY 2010.

Q: The company has increased restructuring expenses this time from ¥8 billion to more than ¥10 billion. Should we understand that this is in order for cost synergies to realize their ¥24 billion targets in the medium-term management plan? Or, is it possible that the company will realize cost synergies of more than ¥24 billion?

A: In the second half of FY 2007, cost synergies of ¥1.3 billion occurred. The prospect is for cost synergies of ¥10.2 billion in FY 2008 for the accumulated total of ¥11.5 billion. We recognize that we are progressing as per the plan towards the target of ¥24 billion. The increase in extraordinary losses this time was the result of revising matters, such as the revision of the costs for the relocation of the Hirakata Research

Laboratory that were incorporated in the budget in the first half of the year, and the costs for the merger with Chosei Yakuhin that were not incorporated in the first half budget.

[Development situation]

Q: What is the development status at Nycomed of roflumilast? If bridging is possible with Nycomed's phase 3 clinical study, should we understand that the company are going to apply for the approval making use of the data?

A: In regard to roflumilast, the results of the monotherapy study and combined administration study that Nycomed implemented for COPD overseas were announced by that company on October 28. Both studies confirmed efficacy in the primary endpoints, including improvement of pulmonary function and reduction of the exacerbation rates. Accordingly, Nycomed has announced that it plans to file NDA for COPD in 2009 so the company would like to investigate the data. The company is conducting phase 2/3 studies in Japan and plans to file NDA with the results of those studies and the overseas data. Nycomed's progress has been delayed, but we will receive the Nycomed application data package for next year and discuss the application in Japan. The data has not yet arrived at present, so I would like to decline to further comment, today.

Q: Is COPD definitely going to be the first indication?

A: While Nycomed conducted development for asthma and COPD previously and the additional study was conducted only for COPD. Consequently, the application would only be for COPD, we suppose. The decision on what to do about asthma will be made by Nycomed from here on.

Q: With FTY720, are the doses in the phase 3 study being implemented now 0.5 mg and 1.25 mg? What is the timing for the release of the Freedom study results and other study results?

A: The doses in the Freedom study are 0.5 mg and 1.25 mg. As for the future schedule, it is difficult for the company on its own to talk about development plan under the license agreement with Novartis. They say that they are able to make an application by the end of next year, however, basically, I cannot raise any clear timing about when the study results will appear.

Q: T-0047 is in its phase 2 study overseas, but have clinical studies begun in the U.S.? Should we think that phase 3 studies would implement simultaneously in Europe and the U.S. from 2009? Is there any change to the schedule?

A: The schedule has not changed. GSK will investigate from now on whether or not phase 3 studies will carry simultaneously in Europe and the U.S. next year, but at present, development is progressing in areas other than the U.S. If the current phase 2 studies can be put together, the project would be able to progress to the next stage in the U.S. too.

Q: It was explained that the phase 2 study for MP-424 has finished, and POC study of phase 3 is carried now. Should you file NDA after the phase 3 study completed? Or, is it possible to make an application while the phase 3 study is still ongoing?

A: It is a condition that the phase 3 data must be finalized. However, there are social demands and we will consult the authorities about the application considering in what kind of data have appeared in what kind of form.

Q. In regard to TA-7284, there are two phase 2 studies that Johnson & Johnson is conducting overseas. One of those is on obesity and I recall that the completion date is October or November this year. Have the data been obtained already? Will the next stage be Phase 2b?

A: We expect that the results will appear earlier, but Johnson & Johnson, our partner, has not disclosed the information so we do not make any comment in regard to timing and stages of development.

[Developing overseas pharmaceutical operation]

Q: In regard to the in-house sales operations in the U.S. and Europe, applications are scheduled for 2010 onwards, but could you describe specific corporate action including alliances with other companies and the acquisition of medium-sized American companies?

A: We are investigating the directions for 2009 while watching the state of progress of Phase 3 development. Basically, we are planning to launch products by our own sales operations, but if there are good projects, we could always look at M&A with other companies. Nothing has been decided at the present time.

Q: I have heard that the company is investigating M&A overseas in about 2009.

Recently, stock prices of American companies are lower. Are you aware of this?

A: We do sometimes receive introductions of that type from investment banks. If it is a listed company, the shares have fallen, but in the case of non-listed companies such as ventures, it is difficult to assess the corporate value. For example, when evaluating development products at their net present value, we feel hesitant about proceeding any further with discussions because we start to evaluate in areas that are not reflected in current share values.

Q: What is the specific timing of MP-146 (Kremezin) in the U.S.?

A: We do not disclose any concrete schedule. We have plans to file 3 projects (MCI-196, MP-146 and CTA018) in the 1 to 1-and-a-half year interval from now on, and we will aim for and push ahead sequentially with developments.

Q: I would like to ask the development of Kremezin. We can say the dialysis is niche market, but if the target expands to stage 3 or 4 CKD patients including patients prior to the dialysis, will comparatively large sales power be required?

A: Kremezin suppresses the patient's transition from stage 4 to stage 5, and the primary endpoint of the clinical studies also targeted suppressing transition to dialysis and kidney transplant. In terms of patients for Kremezin is targeted at stage 4 or slightly lower. The range of subject patients will expand in comparison to Cholebine and CTA018. However, if we consider MRs promotion activities for 3 products at the same hospital, we are able to perceive it as one concentrated strategy. We will investigate from now on what form to construct the sales strategy in. We expect it will grow big business.

[Other]

Q: When will the strategy be clarified in regard to Choseido business operation?

A: The company acquired the majority of Choseido's stock in the first half of the year, but management has not yet been consolidated in these results. We are investigating business model of generic drugs. The difference is that Choseido sell through its distributors and we sell through wholesalers. In FY 2009, the company plans to combine the Choseido's sales subsidiary and Tanabe Seiyaku Hanbai. Consequently, we would like to put together the generic drug business strategy by spring next year.

Q: Choseido has factory facilities, and will they keep them going?

A: Choseido has 3 plants: one exclusively for antibiotics, one for general formulations and its subsidiary plant, Hoshienu Pharmaceutical Co., Ltd. As plants are specializing in generic drugs and small-order manufactures and Choseido has manufacturing approval, we would like to make effective use of these facilities.

Q: I would like to ask about the company's generic drug strategy. Companies such as Meiji Seika that sell products cheaply seem to be successful. Mitsubishi Tanabe has said it will not sell products cheaply, but is it possible that strategy will change in the future?

A: We will pursue generic drug business not with a policy of selling the products based on their price differentials, but with a policy of good quality at low cost, and we will run sales activities with customers at appropriate prices for generic drugs. Our concept in regard to sales methods is different to that of the companies that are successful at the moment. It seems that the policy of the big generic companies is also not to sell cheaply.

Q: Will the company not respond even if the demand of medical facilities is based on price?

A: We think that there are costs required in order to provide reliable generic drugs and also, that stability of prices is required in the generic drug market. We do not want to operate in the form of just selling cheaply and then giving up as profits dry up, but want to operate steadily and sustainably.

Q: The total market value of the company now exceeds that of the parent company, Mitsubishi Chemical Holdings. Previously, Mitsubishi Chemical and Mitsubishi Pharma merged. Does such problem come up to the surface between the parent company and subsidiary?

A: The Company was formed and started under the agreement that the Company will remain listed, and Mitsubishi Chemical Holdings will, in principle, maintain its shareholding ratio in the Company for the next 10 years.