

Q&A, FY2008 Business Results Briefing

6:00pm - 7:00pm, Friday, May 8, 2009

[Attendees]

Kunihiko Shimojuku, Board Director, Executive Vice President

Ken-ichi Yanagisawa, Board Director, Managing Executive Officer

Junji Hamaoka, Board Director, Managing Executive Officer

Kenkichi Kosakai, Executive Officer, General Manager, Finance & Accounting Dep.

[FY2009 Forecast]

Marketing

Q: The Company has forecast sales of 9 billion yen in generic business for fiscal year (FY) 2009, increase of 5 billion yen in year-on-year comparison, but how much of an increase is expected in terms of income?

A: We expect to have a slight loss at the operating income stage.

Q: The Company is planning on an increase in sales of Anplag in FY 2009. Should we understand that the Company does not think it possible that the generic drugs will be released?

A: That is correct.

Q: Has the approval for a change of dosage and usage (dose escalation) for rheumatoid arthritis (RA) been incorporated into the FY 2009 sales forecast for Remicade?

A: The Company drew up the sales plans in the expectation of acquiring approval during FY 2009. That is why the sales plan of Remicade increase in the second half of the year.

APIC

Q: What level of impact will there be on operating income and ordinary income due to the transition of API Corporation into an equity method affiliated company?

A: You would find the operating income of API Corporation in page 7 of "Supplement" for "Financial Results for FY2009."

R&D Expenses

Q: The Company has explained MP-424 related expenses as a factor in the increase of R&D expenses in FY 2009. Could you explain this in slightly more detail please?

A: We are currently in discussions with the licensor in regard to a partial revision of the agreement and accordingly, anticipate that some considerations will occur singly due to the revision. Because these matters are currently under discussion things like the content of the revision and consideration are uncertain so we will refrain from providing details.

Q: In contrast to the target of 82 billion yen for R&D expenses in FY 2010 given in the medium-term management plan, the Company is planning on R&D expenses of 86 billion yen in FY 2009. Can this increase be considered to be temporary?

A: Part of the increase of 12.9 billion yen in FY 2009, year-on-year basis, was MP-424 related expenses and we think it is temporary.

Q: Should I think the target for R&D expenses in FY 2010 still be 82 billion yen?

A: There has been no change from 82 billion yen as of the present in regard to the target for FY 2010.

Q: FY 2008 finished with part of the budget for R&D expenses unused. Is it possible that R&D expenses will fall below expectations in FY 2009 as well?

A: We think the R&D expenses are progressing as budgeted at the present time. Like FY 2008, some projects that were not incorporated into the initial budget will also crop up during the term so it is not necessarily the case that the expenses will fall.

Retirement Benefits

Q: In regard to retirement benefit liabilities, the pension systems that the former companies ran were integrated from this April. The difference in actual calculation is large too. How large will the impact be on labor costs in FY 2009 including the integration of the periods used for amortization?

A: When FY 2008 and FY 2009 are compared, retirement benefit expenses increase by about 7 billion yen year-on-year.

Of this, 4 billion yen is for amortization of the difference in actual and expected results that occurred in association with the amortization in pension investment during FY 2008. While the Company integrated the pension systems in April this year, the difference in actual and expected results that occurred during FY 2008 will be amortized based on the periods for amortization used at the former companies (5 years at the former Mitsubishi Pharma and 13 years at the former Tanabe).

The remaining 3 billion yen is due to a combination of factors. These included the amortization of the actual gain, to be a reduction of the costs that occurred in FY 2003 at the former Mitsubishi Pharma finished in FY 2008, and a reduction in the rate of expected returns from the former Tanabe pension assets (3.5% → 2.5%) due to the integration of the pension systems. Past service liabilities generated in association with future differences in actual and expected results and the integration of the systems will be depreciated over 10 years.

Other Questions

Q: The Company left out income from licensing fees that was incorporated in the initial plans for FY 2008 from the FY 2008 forecast given at the time the 2nd quarter business results were announced. Having checked the business results this time, it seems this income was not recorded. Are these projects still running?

A: Yes, they are. The policy of the company in regard to income from licensing fees is to incorporate them in budgets based on conservative forecasts. There are several new candidate products for licensing, but we have decided that we will not include any that have not been confirmed in results forecasts.

Q: Results for FY 2009 are expected to be ordinary income of 63.5 billion yen, extraordinary losses of 4.5 billion yen, pre-tax income of 59 billion yen and current term net income of 32.5 billion yen. The tax burden ratio for company tax, etc, is at 44%, about the same level as FY 2008, but because extraordinary losses will be low in FY 2009, pre-tax income will be higher than in FY 2008. There are also tax deductions for experiment and research expenses so should the tax rate decrease further?

A: In FY 2008, there were some factors that served to increase the rate of company tax, etc, but due to the revision of the tax system in FY 2009, the Company has liquidated deferred tax liabilities related to the retained earnings of overseas subsidiaries at the annual closing of accounts in FY 2008. As a result, the rate of company tax, etc, fell by a proportionate amount. Accordingly, we do not think that the forecast of the burden ratio for company and other taxes in FY 2009 is high.

Q: Will special deductions for experiment and research expenses increase in FY 2009?

A: Even if experiment and research expenses do increase in the accounts for FY 2009, it is not the case that the Company can deduct all of the expenses, but up to the limit.

[Shareholder Returns]

Q: In regard to shareholder returns, the Company aims at a dividend payout ratio of 35%, but partly because income fell below expectations in FY 2008, the dividend payout ratio was higher than this target and there seem to be some investors feel a risk that the rate of returns will fall in the future. The forecast for FY 2009 is 36.9%, meaning that the rate will continue above the target of 35%. Should we understand that the Company does not consider dividends to be too high?

A: The Company believes that the stability of dividends is an important factor for stakeholders, shareholders in particular. Because extraordinary losses will fluctuate greatly on account of problems such as negative inheritances and structural reform associated with the merger, there will probably be some terms when the dividend payout ratio will fluctuate greatly as a result. However, the Company should handle those fluctuations internally without passing the impact on to shareholders as much as possible. In that sense, as we foresee an income decline in FY2009 by transient factor caused by increased R&D expenses, we do not feel uncomfortable even though a dividend payout ratio exceeds 35% in FY2009.

[Medium-Term Management Plan]

Q: Do you see the Company being able to achieve the operating income of 95 billion yen targeted for FY 2010 at the present time?

A: The Company raised sales of 460 billion yen and operating income of 95 billion yen for FY 2010 in the medium-term management plan, but since that time, the domestic market for ethical drugs has continued to worsen more than we anticipated, including an increase in the number of facilities that have adopted DPC, the development of policies promoting the use of generic drugs and the subdual of doctor consultations due to economic recession. Moreover, in addition to multiple unforeseen factors such as the increase in R&D expenses and the increase in retirement benefit costs due to the deterioration of pension fund operations, we also have the transition of API Corporation into an equity method affiliated company. We are well aware that the gap between our planning and actual results has grown considerably. However, the 5 priority issues raised in the medium-term management plan are developing largely according to plan and we know that we are moving ahead steadily in the direction we are aiming for.

[Medway]

Q: In regard to Medway, should we understand that the Company is aiming basically to restart shipments of the 25% preparation?

A: We are currently undergoing the on-site investigation of the Ministry of Health, Labour and Welfare. Investigation of the cause and preventing reoccurrence are the pressing issues for the Company and we cannot give you an answer at the present stage in regard to the restarting of manufacturing or shipments.

Q: The Company has explained that it has set up Medway Issue Measure Committee, and who are the members of that committee?

A: The Committee is chaired by Tsuchiya, Board Director, Executive Vice President, and is composed by Shimojuku, Board Director, Executive Vice President, and some other members including Executive Officer, Corporate Management, and Executive Officer, Pharmacovigilance & Quality Assurance, and so on. It is anticipated that in future, the investigation of reoccurrence prevention will extend to issues such as corporate culture and the like, and when we reach that sort of stage,

we think that we will also ask people from outside of the Company to participate as committee members.

Q: An investigation by the authorities has begun for the Medway issue. I think that depending on the case, these kinds of issues can even result in the administrative sanction of suspension of business. Have such factors been incorporated into future budgets?

A: The decrease in sales of Medway has been incorporated. The Company is not in a position to comment on things like the details or possibility of sanctions.

[Development]

FTY720

Q: In regard to FTY720, there was a presentation at the meeting of the American Academy of Neurology (AAN) last week on the results of TRANSFORMS and Novartis AG held a conference call for the result of the study. Melanoma developed in 3 cases as adverse events in that study at the low dosage of 0.5mg for FTY720. I would like your opinion on this.

A: We obtained information in advance on the Novartis AG announcements on April 29 and May 1 and have a full grasp of the details. There has not yet been a meeting between the two companies in regard to FTY720 after their announcement so we only have knowledge based on the details of the announcements at the present time. We have been able to confirm fully that the drug is effective in the study for 1 year. In regard to safety, issues such as infection and a decrease in heart rate, etc, have been reported. Melanoma definitely only occurred in the 0.5mg group, not in the other IFN group or 1.25mg group. Novartis AG also put in place a thoroughgoing monitoring system using specialist dermatologists after melanoma was found in the phase 2 study. Since then, the continued phase 2 study has currently been running for 4 years, but there has been no occurrence. Accordingly, the 2-year data for the study currently underway will be made open in the future, and issues such as the events among cases receiving long-term administration will be available, and since it is apparent that FTY720 has a very high benefits, we think that from a risk and benefit perspective, the product value of this drug will probably be determined.

Q: In regard to cladribine, the treatment drug for multiple sclerosis that Merck KGaA is developing, that company is planning to file an NDA in about the middle of this year, which is about half a year earlier in comparison to FTY720. What do you think in regard to the competition with this drug? Also, it seems that Merck KGaA is also conducting a study for combination of cladribine and IFN- β , but is the Company planning to conduct such a study for FTY720?

A: At present, we understand that the studies being conducted are all of the studies that will be conducted for FTY720, and NDA will be filed by using those results. We know the details of the announcement in regard to cladribine. We are analyzing the situation based on that information while holding meetings with Novartis AG. Although we understand that according to the announcement made by Merck KGaA, they are working at a slightly faster than us, we hope that our product will obtain the approval earlier than cladribine as an oral agent. However, cladribine is one that can also be used in the treatment of leukemia and has a cytotoxic effect that destroys lymphocytes, while FTY720 conversely restricts lymphocytes to the lymph node and reduces circulating lymphocytes so it does not destroy lymphocytes. Consequently, they are completely different between the drugs in the mechanism of action. We think it will be an issue in the future whether cladribine will be positioned as a strong competitor.

Q: I am aware that Merck KGaA has not conducted a comparative study with Avonex. What do you think?

A: We cannot refer to the clinical studies for another company's drug.

Q: Novartis AG has released its schedule for filing an NDA for FTY720 during this year, but will the FREEDOMS study be included in the application package?

A: We understand that it will be. The schedule is for the current studies to be made open during this year. We understand that Novartis AG will then prepare the package and apply to the regulatory authorities.

Q: When will the results of FREEDOMS study be open?

A: We cannot mention about that. We understand that Novartis AG will file NDA during this year.

Q: Have you forecast the milestones in association with the NDA?

A: We refrain from making comments on the economic conditions.

Roflumilast

Q: Nycomed has announced that they will file NDA for Roflumilast in Europe and will soon do the same in the US too when it finds a partner. I would like you to give an update on future development in Japan.

A: We are aware of the progress made by Nycomed. We have asked for data from Nycomed and are currently carrying out a complete check.

Q: Will we be able to hear more about this in upcoming IR Meeting scheduled on May 25?

A: We are currently in discussions with Nycomed in regard to our future policy and what we can say depends on the progress of those discussions.

CNTO148

Q: According to JAPIC, the Japanese clinical study for golimumab (CNTO148) has ACR20 improvement at Week 14 as a primary endpoint. Is that correct?

A: Yes, that is correct.

Q: Phase 2/3 studies began from May 2008. Patient recruiting for one study of them has finished so should we think that the NDA for golimumab will be filed in Japan during FY 2009 or will it be further in the future?

A: Golimumab is being developed jointly with Janssen Pharma and the clinical trials are progressing steadily. We cannot give you information in regard to the timeline because of the partnership with Janssen Pharma.