

Wednesday, October 19, 2011 from 16:00 to 17:30 [Attendees]

Michihiro Tsuchiya, President and Representative Director

<u>Kuniaki Kaga,</u> Representative Director and Managing Executive Officer, General Manager of International Business Unit, International Strategy & Operation

<u>Kenichi Yanagisawa</u>, Board Director and Managing Executive Officer, Division Manager of Sales & Marketing Division

<u>Kenkichi Kosakai</u>, Board Director and Managing Executive Officer, Business Management

Masayuki Mitsuka, Board Director and Executive Officer, Global Product Strategy, General Manager of Global Product Strategy Department

<u>Takashi Kobayashi</u>, Board Director and Executive Officer, Corporate Strategic Planning, General Manager of Corporate Strategic Planning Department

Seiichi Murakami, Executive Officer, Division Manager of Development Division

[Numerical Targets]

FY2015 Numerical Targets

- Q/ You set net sales of ¥500 billion and operating income of ¥100 billion as business performance targets for fiscal 2015. What is your expectation for the achievement of these targets?
- A/ We are determined to achieve these performance targets with operational efforts and strong will. NHI prices for our new products have not determined yet and there are many other uncertainties in our business environment. Please understand that these targets are set based on certain preconditions.
- Q/ You set operating income of ¥100 billion and the overseas operating income ratio at 40% as the business performance target for fiscal 2015. This means that the operating income in Japan will be ¥60 billion. Your forecast for operating income in fiscal 2011 is ¥68 billion. Does this mean that operating income in Japan will decrease in the next five years?
- A/ The operating income forecast of ¥68 billion for fiscal 2011 includes operating income overseas (including royalty income) and operating income from the blood plasma fractions business which we have been implementing business integration with the

Japanese Red Cross Society. In addition, the operating income ratio for fiscal 2015 is calculated on the basis that all the R&D expenses overseas are borne in Japan. Accordingly, the operating income will not decrease. The current medium-term management plan takes into account the decrease in operating income resulting from two NHI price revisions during the plan period. However, we will maintain the profitability within Japan by covering this negative impact with introduction of new products into the market.

- Q/ What is your expectation for the royalty income from FTY720 (Gilenya)?
- A/ We expect royalty income slightly less than ¥40 billion in fiscal 2015. This includes, in addition to FTY720 (Gilenya), other royalty incomes in Japan and overseas including Argatroban and Tanatril, Herbesse and new royalty income from TA-7284 that is expected to be introduced in the U.S. and European markets in the future. The calculation assumes that the exchange rate is ¥85 for one dollar. Sales forecast for FTY720 (Gilenya) is calculated based on our independent estimation. We are sorry but we cannot comment on royalties from individual products sales.
- Q/ Do you have an ROE target for 2015?
- A/ The Company will place emphasis on the business growth for the five years. We do not include ROE in the performance targets. ROE in fiscal 2010 was 5.5%. If the current medium-term management plan is achieved, we expect that ROE will exceed 7%.
- Q/ To what extent sales by Bipha (Medway) is included in your current medium-term management plan?
- A/ We are now working on preparation to resume the manufacture and sales of Medway. The management plan assumes that the business will be resumed by fiscal 2015.

Investment Plan

- Q/ You plan to make investments of more than ¥100 billion in five years. What do you plan to invest in? What is your expectation regarding the increase in depreciation expenses resulting from the investments?
- A/ We will invest in large-scale facilities and equipment for manufacturing bulk substances and drug products, in order to consolidate the production function into those large facilities. We also consider constructing a new research building into which the research function will be consolidated. We do not expect significant increase in depreciation expenses.
- Q/ Do you have a plan to consolidate production facilities (currently 7 plants in Japan)?
- A/ As for the consolidation of production facilities, we will develop a specific plan from now on. The Company manufactures a large number of products. To proceed with the

consolidation smoothly while maintaining the stable supply of these products, some consolidation plans will be started during the current medium-term plan period and some plans will be implemented in the next medium-term period.

Q/ Of ¥100 billion for the investment plan, how much do you expect to use for in-licensing? A/ We expect that about 30% will be used for in-licensing.

Dividend Policy

- Q/ You set the target of 40% pay-out ratio. When will the ratio be increased? If the profit for the current year become higher than forecast, will the dividend be increased? If the profit decreases in the future, will the dividend be also decreased in accordance with the policy of the 40% pay-out ratio?
- A/ We will increase the pay-out ratio as soon as possible once we establish the profit-making foundation and confirm its viability. The Company targets to achieve operation income of ¥100 billion in fiscal 2015. In addition to the increase of the pay-out ratio, we believe the dividend amount can also be increased by improving the absolute profit values. Our basic policy is to maintain stable returns to shareholders while making investments for the future growth. Thus, even if the profit decreases sharply, we will not decrease the dividend amount in accordance with the policy of the 40% pay-out ratio. Summation of figures for the current second quarter are still in progress. We will decide the dividend policy for the current year based on forecasts for the remaining period.

[Bolstering Our Ability to Discover New Drugs]

- Q/ You have set up the target in the current medium-term plan to introduce 10 products in the market. Do you have back-up scenarios for possible risks?
- A/ Excluding already approved or marketed products (i.e. SIMPONI, Telavic, Imusera and Acref), risks associated with the development have been considered for six products. If the risks arise and it becomes difficult to achieve the target numbers, we will make all efforts to achieve the target number, including acquiring sales rights for other companies' products.
- Q/ What do you mean by saying "challenge in new chemical spaces (such as turning macromolecular pharmaceuticals into smaller molecules)?
- A/ For example, in the area of protein-protein interaction, such as antibody drugs, regulation of transcriptional factors, and intracellular signal transduction system, etc., it is difficult to create new drugs from traditional low-molecular compounds. With the advance in technology, while maintaining the activity of antibody molecules, it becomes possible to reduce its molecular weight to a low-molecule level, and protein-protein interaction can

be controlled with special low-molecule compounds. By combining such technologies with our medicinal chemistry technology, we can create new low-molecule compounds and a shift from I.V. to oral agents can be possible. We are eager to challenge these new fields.

[Advancing Domestic Operations, Centered on New Products]

- Q/ What is your plan for the number of MRs and the sales organization in Japan?
- A/ Currently, we have 2200 MRs under the Group in Japan (including Yoshitomi Yakuhin, Tanabe Seiyaku Hanbai, and Benesis). Mitsubishi Tanabe Pharma has 1,700 MRs in Japan (including specialized MR). During the current medium-term management plan period, we plan to introduce many new products into the market, in addition to Remicade and other existing priority products. In the current traditional sales organization, we are now facing some shortage of the sales workforce. Sales activities with very high quality are currently needed to satisfy "unmet medical needs." In such a situation, we will shift to a new sales organization that can surely provide information to customers without the expansion of the current MR resource size.

Remicade and SIMPONI

- Q/ Does Remicade sales forecast include the impact of biosimilars?
- A/ We understand that biosimilars have been developed in the rheumatoid arthritis field. However, approval criteria in Japan are still uncertain. We do not believe that they become a big threat for us during the current medium-term period.
- Q/ What impact do you expect from the revision of Remicade NHI price?
- A/ As for the impact of NHI price revisions on the current medium-term management plan, we have considered the past rules for NHI price revision, our past experience and various countermeasures we had taken in the past against NHI price revisions. We take the same actions for Remicade.
- Q/ What is your forecast for Remicade and SIMPONI in fiscal 2015?
- A/ As our marketing policy, we will not shift from Remicade to SIMPONI. We will continue our efforts to achieve strong growth of Remicade sales, while adding SIMPONI subcutaneous injection agent to the line-up to respond to the various patients' needs. Like Remicade, once SIMPONI grows into a large-sales product by the expansion of indications, we believe that we can maintain the sales growth with the two biologics agents. We aim at achieving ¥100 billion combined sales of Remicade and SIMPONI as early as possible.

Telavic

- Q/ I understand that cooperation with dermatologists is essential for Telavic. During the all-patient post-marketing surveillance, can Telavic be administered only in facilities where the department of dermatology is operated?
- A/ As a condition for the all–patient post-marketing surveillance, it is required that the drug be administered in facilities where dermatologists station or facilities that have affiliated dermatologists outside the facilities. Since the drug will be needed by many patients and medical facilities, we will complete the all–patient post-marketing surveillance as quick as possible and expand the facilities where Telavic can be administered.

Q/ How many cases are there in the all-case research?

A/ 3,000 cases.

MP-513 and TA-7284

- Q/ How is the status of the development plan for the combination drug of MP-513 and TA-7284 for diabetes treatment?
- A/ These drugs are a DPP4 inhibitor and a SGLT 2 inhibitor. Since both drugs can be a base agent for diabetes treatment, the combination of the two drugs and a combination of each drug with another drug will be possible. The basic review has already started.

[Building a Foundation for the Expansion of overseas Operation]

Area Strategy

- Q/ In the developed market (the U.S. and Europe), do you plan to expand the business by your own operations, not by M&As or strategic alliance?
- A/ In the fields of rare diseases and kidney diseases, we can develop the business with relatively small resources. Accordingly, we believe that growth by our own operation is possible. On the other hand, in the fields of drugs that require extensive resources, such as drugs for circulation and metabolism diseases, we will adopt an approach suitable to each drug, including joint development and sales consignment, considering the maximization of product values and timing merits.

M&A is just one of means to expand the business. We will decide whether to use M&As or not, considering what we want to acquire and evaluating the investment effect carefully. Certain requirements must be met. For example, the target company must possess a new drug seed and technology we need, or our product must be able to be marketed through the target company's sales network. We will not pay a big ticket

- thoughtlessly but consider business expansion approaches suitable to our current status.
- Q/ Don't you consider the option to discontinue expansion by your own operation in the U.S.? If the Company aims to become a global specialty pharma, we can understand that in-house development is necessary. But is it necessary to conduct marketing by yourself?
- A/ The development of MP-146 has progressed. There is also TRK-820 whose in-licensing was announced on October 14. At present, we will continue business expansion through our own operations. The U.S. market is an advanced market. To become a global specialty pharma, and to learn about the handling of medical information, know-how and skills on marketing and sales, we would like to take the approach to expand the business through our own operations.
- Q/ The medical system reform is being implemented in the U.S. What impact do you expect on the kidney diseases and dialysis treatment areas?
- A/ In the dialytic therapy area, the prospective payment system will be adopted for solid agents in 2014 and the impact of this system on our sales is concerned. However, MP-146 under development is intended for patients who have not started the dialysis treatment. Moreover, as the drug is for an "unmet" field, we do not believe that the impact is significant.

MP-424 (China)

- Q/ According to your presentation material regarding the development schedule of MP-424 in China, you schedule the introduction of the drug in the Chinese market after the current medium-term period. Don't you have any plan to accelerate the schedule?
- A/ We have acquired CPP (certificate of pharmaceutical product) and the IND examination has completed. Clinical tests are carried out currently. We expect that the product will be introduced into the Chinese market in 2016.
- Q/ What is the status of the development of chronic hepatitis C treatment drugs in China?
- A/ We do not know very much about this matter. But we heard that an application for clinical trial permit has been filed for a certain compound. Compared with that compound, we understand that the development of Telavic is a little bit behind.
- Q/ As for the introduction of a new hepatitis therapy drug, do you plan to develop just oral drugs for a combined therapy for chronic hepatitis C?
- A/ We will proceed with intensive development of MP-424 in China. In addition, we are examining several other alternatives, aiming to create synergies in the hepatitis treatment field.

MT-1303 (the U.S. and Europe)

- Q/ Will you conduct joint development with Novartis regarding MT-1303 which is the successor of FTY720?
- A/ As for S1P receptor functional antagonists, such as FTY 720, we believe that they can be developed as drugs for autoimmune diseases in addition to multiple sclerosis. We cannot make any comment about future partners at this time. First, we would like to proceed with the in-house development.

[Accelerating Operational and Structure]

Generic Drug Business

- Q/ You set the ¥50 billion sales target for the generic drug business for fiscal 2015. How will you achieve this target? What is the ground for ¥50 billion?
- A/ As for the generic drug business, it is difficult to achieve the sales target of ¥50 billion just by transferring long-listed products from Mitsubishi Tanabe Pharma to Tanabe Seiyaku Hanbai or by selling generic drugs after the expiry of patents of competitors' large-sales products. Collaboration with other companies is necessary. To show the presence of our generic drug business in the Japanese market, we believe we need to sell ¥50 billion at minimum.
 - At the time of expiry of the patent for a large-sales product, around 20 to 30 companies would start selling generic drugs. It is also important to acquire the market share quickly in such situation. To achieve quick acquisition of the market share for our generic drugs, we will utilize the marketing force of Mitsubishi Tanabe Pharma and Yoshitomiyakuhin, as well as Tanabe Seiyaku Hanbai which is engaged in sales of generic drugs.
- Q/ I understand that in the reviewing for the next NHI price revision, the Central Social Insurance Medical Council of the Health, Labor and Welfare Ministry is considering another reduction of the NHI prices of long-listed drugs, following the previous price revision. How do you reflect the NHI price revision rate for long-listed drugs in your sales forecast? What impact do you expect on the generic drug business?
- A/ In the previous NHI price revision, all long-listed drugs prices were additionally reduced by 2.2%. This revision rate is taken into account as one factor when we forecast the possible impact on sales.
 - Considering this trend, we are transferring the sales business of long-listed drugs from Mitsubishi Tanabe Pharma to Tanabe Seiyaku Hanbai, aiming to establish a low-cost operation. We plan to build a revenue/profit structure in five years to increase the overall

profit of the Mitsubishi Tanabe Pharma Group.

[Others]

- Q/ As for the previous medium-term management plan 08-10, why couldn't you achieve the numerical performance targets (net sales and operating income) for fiscal 2010?
- A/ These targets could not be achieved mainly because the consolidated subsidiary (engaged in bulk substance, medical intermediates and fine chemical businesses) were excluded from the consolidation due to the transfer of capital stocks, the impact of the NHI price revision was greater than expected, and market introduction of new products overseas was delayed.