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Message from the President



Fiscal 2010 is positioned as a year for leveraging qualitative and quantitative improvements. Moving forward, those improvements will drive further progress under the next medium-term management plan.

Strong sales growth was recorded by core product Remicade, and we made favorable progress in the development of promising new drugs.

Introduction

As a result of changes in the social structure, the management environment for pharmaceutical companies is becoming increasingly challenging, and due to the direction of medical system reforms, pharmaceutical companies that cannot continually discover new drugs will not be able to survive. In this setting, the Group formulated a three-year management plan, the Medium-Term Management Plan 08–10, and worked to realize its corporate philosophy and vision. Two years have passed, and we are now seeing the success of our efforts to enhance our R&D pipeline and strengthen domestic marketing. However, we still face a number of challenges, such as the Medway injection incident. To resolve these challenges as well as new issues that arise from changes in the internal and external environments, the entire Group will work to “build strengths” and “increase productivity.” In this way, we will improve our competitiveness and position in fiscal 2010, ending March 31, 2011, as a year for leveraging qualitative and quantitative improvements. Moving forward, those improvements will drive further progress under the next medium-term management plan.

Overview of Fiscal 2009

Looking at consolidated results for fiscal 2009, ended March 31, 2010, net sales were down 2.4%, to ¥404.7 billion. The principal reason for the decline in sales was the fact that Company sold a portion of its holdings of shares in API Corporation (APIC), and as a result APIC changed from a consolidated subsidiary to an equity-method affiliate. This change had the effect of reducing sales by ¥25.7 billion year on year. Excluding this change, we recorded an effective increase in net sales.

This effective increase was attributable to an increase in domestic sales of ethical drugs, which rose 5.7%, to ¥354.6 billion, basically in line with our plan. Especially strong sales growth was recorded by core product Remicade. Sales of Remicade were up 26.2% in fiscal 2009,

to ¥47.2 billion. Our efforts to maximize Remicade's product value are steadily generating results. Favorable performances were also recorded by other products, such as Talion and Maintate. In addition, sales of vaccines increased by a large margin due to the launches of the H1N1 HA flu vaccine and a freeze-dried, cell-culture-derived Japanese encephalitis vaccine. Sales of generic drugs also increased. Operating income was down 14.3%, to ¥61.5 billion, while net income rose 14.0%, to ¥30.3 billion.

In addition, in fiscal 2009 we saw tangible results from a range of initiatives. For example, we made favorable progress in projects linked to the discovery of future growth drivers. In December 2009, Novartis Pharma, of Switzerland, filed new drug applications (NDAs) in the U.S. and Europe for FTY720 (multiple sclerosis), which it licensed from the Company. FTY720 is now in phase 2 trials in Japan. Also, TA-7284 (diabetes mellitus) is in phase 3 trials overseas conducted by Johnson & Johnson, which has licensed it from the Company, while in Japan, phase 2 trials for TA-7284 were commenced in November 2009. In addition, favorable progress is being made in the development of such promising new drugs as MP-424 (chronic hepatitis C) and MP-513 (type 2 diabetes mellitus). In January 2010, we signed an agreement with Mochida Pharmaceutical, of Japan, for the co-marketing in Japan of the antidepressant Escitalopram. Each of these drugs has the potential to become a major product, and we expect them to become drivers of our future growth. We are seeing solid results from our efforts to promote the discovery of new growth drivers.

Medway Injection Incident

In April 2010, Mitsubishi Tanabe Pharma and its consolidated subsidiary Bipha received an administrative action—suspension of business and an order for improvement—from the Minister of Health, Labour and Welfare in regard to a violation of the Pharmaceutical Affairs Law. There were two main reasons for the action. First, the Company, a manufacturer and marketer, manufactured and sold the ethical drugs Medway Injection 5% and Medway Injection 25% without ensuring that Bipha, the manufacturer, appropriately implemented manufacturing control and quality control. Second, the New Drug Application (NDA) materials for those products that were submitted by the two companies contained materials that were based on fraudulent acts by Bipha. Having received this administrative action, the Company has revised its management system to further clarify its social responsibilities. Moreover, directors and corporate auditors have agreed to voluntarily return a portion of their compensation.

We are taking the recent administrative action very seriously. We have reflected deeply on the actions that led to a loss of society's trust, and we offer our sincere apologies to patients, medical professionals, and the rest of society.

For companies, the trust of society is the foundation of business activities. In addition to the direct corrective and improvement measures that we have formulated in regard to the inappropriate activity related to the Medway Injection, in accordance with the business improvement plan that we submitted to the Minister of Health, Labour and Welfare in June 2010, we will implement thorough countermeasures to prevent a recurrence of such an incident, and we will do our utmost to regain the trust of patients, medical professionals, and the rest of society.

(Information about the Medway Injection problem and the business improvement plan is provided in the CSR Report 2010 and on the Company web site.)

As a company engaged in the life sciences, we are taking the recent administrative action very seriously.

For fiscal 2010, we are forecasting results that fall short of our management objectives. We are, however, achieving steady results, centered on our key management issues.

Progress of the Medium-Term Management Plan 08–10

Fiscal 2010 will be the final year of the Medium-Term Management Plan 08–10. As numerical targets, we have worked to achieve the fiscal 2010 management objectives that are outlined in the plan. However, due to changes in the internal and external environments, such as the removal of APIC from the scope of consolidation, and the Medway Injection incident, we are forecasting net sales, operating income, and net income that are short of our fiscal 2010 management objectives. On the other hand, we are achieving steady results, centered on our key management issues—enhancing the Company’s domestic sales presence, steady progress in key development projects, progress in developing overseas pharmaceutical operations, progress in generic operations, and creating an efficient organization and cost structure.

Strengthening Domestic Marketing

In the medium-term management plan, the Group has identified six priority products—Remicade, Radicut, Anplag, Urso, Talion, and Tanatril. We have worked to expand the sales of these products by effectively utilizing our medical representative (MR) workforce, which is one of the largest in Japan. As a result of increases in the number of MRs specializing in Remicade and in cerebrovascular drugs, progress in the lifecycle management strategy, and advances in the focused promotion of priority products, sales of the six priority products have recorded favorable growth.

Remicade, which has been positioned as the Company’s growth driver in the short term, continues to strengthen its market presence in the face of intense competition among biological agents used in the treatment of inflammatory autoimmune diseases. In July 2009, approval was received for a partial change of dosage and usage for rheumatoid arthritis (RA) (increase of the dosage, shortening of the administration interval) and for a partial change of indications (inclusion of the prevention of structural joint damage). In addition, approval was received for indications of psoriasis in January 2010, ankylosing spondylitis in April 2010, and ulcerative colitis in June 2010. Remicade has grown into an innovative drug that can change the natural history of diseases that had been intractable. In the treatment of rheumatoid arthritis (RA), for example, Remicade has the potential to inhibit the progression of joint damage and to induce clinical remission. In addition, it is now becoming possible to reach the point where biological agents are no longer necessary (biologic-free remission), and even reach the point where all drugs are no longer necessary (drug-free remission). In the pharmaceutical industry, there is a practice known as fostering of drugs which means post-marketing development of drugs, and Remicade is such a drug. The latent potential of Remicade has been leveraged through the evaluation of its efficacy and safety and the consideration of its dosages and administration intervals. As a company that handles RA drugs, we will continue working to help patients suffering from RA. In fiscal 2010, sales of Remicade are expected to substantially exceed the fiscal 2010 target of ¥50.0 billion that is included in our medium-term management plan. However, this is simply a transit point. Targeting the achievement of even higher goals, we will continue working to maximize the product value of Remicade.

In addition, we will strengthen links with Group companies, such as Yoshitomiyakuhin, which handles psychiatric medications; Benesis, which conducts fractionation products business; and Tanabe Seiyaku Hanbai, a generic drug sales company. We are also aggressively leveraging strategic alliances.

Steady Progress with Promising Development Projects

Targeting the launch of growth drivers from fiscal 2011, we are making steady progress in promising development projects. In December 2009, Novartis Pharma filed NDAs in the U.S. and Europe for multiple sclerosis (MS) treatment agent FTY720, which it licensed from the Company. TA-7284, meanwhile, is a treatment agent for diabetes, which is a priority disease area for our R&D activities. Johnson & Johnson licensed TA-7284 from the Company and is conducting phase 3 trials overseas. In Japan, phase 2 trials for TA-7284 were started in November 2009. In addition, chronic hepatitis C treatment agent MP-424 is in phase 3 trials in Japan, and diabetes treatment agent MP-513 moved up to phase 3 trials in October 2009. In the U.S. and Europe, the Group is moving forward with phase 3 trials for two drugs in the renal field: MC-196 (hyperphosphatemia) and MP-146 (chronic kidney disease). In addition, phase 3 trials for TA-1790 (erectile dysfunction) have been started in the U.S. and South Korea by licensees VIVUS, of the U.S., and Choongwae Pharma, of South Korea. As one facet of lifecycle management, we are working to obtain additional indications and/or dosage forms for Remicade and Radicut. Additional indications for Remicade are making favorable progress. In January 2010, we also received approval for a new dosage form for Radicut, an IV infusion bag formulation, which we launched in May 2010.

We are also making progress in overseas business. In preparation for the start of sales of MCI-196 and MP-146 through our own U.S. sales network, in July 2009 we established Mitsubishi Tanabe Pharma America. We are implementing pre-marketing activities targeting nephrologists and dialysis specialists in preparation for the launch of MCI-196 and MP-146 from fiscal 2011. Meanwhile, in China, South Korea, Taiwan, and Indonesia, we are taking steps to bolster our operational foundation and expand the range of products sold via the Group's own sales network.

In generic operations, we are working to strengthen our sales system for the supply of generic drugs that are trusted by patients and health care professionals (Reliable Generics) and to quickly establish a robust lineup of these products. In April 2009, Tanabe Seiyaku Hanbai merged with Chosei Yakuhin, a sales subsidiary of Choseido Pharmaceutical, and in October 2009 we completed the integration of their sales organizations. In October 2009, Mitsubishi Tanabe Pharma transferred sales of four long-term listed products to Tanabe Seiyaku Hanbai. In these ways, we have strengthened our lineup of generic products.

Targeting the creation of an efficient organization and cost structure, under the medium-term management plan the Company is working to achieve a cumulative total of ¥24.0 billion in cost savings, and to that end we are moving steadily forward with a range of measures, including base consolidation, restructuring of affiliated companies, and the establishment of a lean, efficient organization and cost structure. In fiscal 2009, as a result of progress in the reevaluation of purchasing, costs, distribution, overhead, and personnel, total cost savings since the merger reached a cumulative total of ¥18.8 billion.

In fiscal 2010, the Company will continue working to restore the trust of society and to achieve key management issues.

What is important is to become a company that can continually provide new drugs.

Preparing for the Next Medium-Term Management Plan

In fiscal 2010, we will continue to advance the action plans that target the achievement of the key management issues of the medium-term management plan. In addition, we will steadily prepare for the next medium-term management plan. More than two years have passed since the merger, and we have made steady progress in enhancing our management system, such as the integration of our personnel systems. As a result, we have steadily grown into a single, united company. In addition, our personnel and financial resources were strengthened through the merger. On that strong foundation, we are making solid progress with action plans targeting the achievement of key management issues in the current medium-term management plan, and are steadily seeing results in the generation of synergies and the advancement of drugs through the development process.

However, we are forecasting results that fall short of our fiscal 2010 management objectives. While it is true that changes in the external environment have had an adverse influence, the fact is that we have had problems specific to the Company. To ensure qualitative and quantitative results from the current medium-term management plan, we must thoroughly understand the current situation and reconfirm this type of problem. First, in regard to the Medway Injection incident, striving to restore the trust of society is an urgent challenge in fiscal 2010. At the same time, we will continue working to achieve key management issues, and the entire Group will work to “build strengths” and “increase productivity.” In this way, we will improve our competitiveness, thereby achieving strong growth under the next medium-term management plan.

Working to Become a Global Research-driven Pharmaceutical Company

I think of pharmaceutical companies as collections of a wide range of functions, such as research, development, production, and marketing. Mitsubishi Tanabe Pharma will strive to become a global research-driven pharmaceutical company by making use of the research foundation and development experience that we have cultivated as we advance cooperative initiatives in a range of fields, such as research, development, production, and marketing.

Our vision of being a global research-driven pharmaceutical company does not mean that we strive to be a company that does everything itself. Global, research-driven pharmaceutical companies do not necessarily have manufacturing and sales bases around the world. What is important is to become a company that can continually provide new drugs. In competing with the overseas mega-pharmaceutical companies, we are constantly considering the optimal method for discovering new drugs and launching them as rapidly as possible, and we will utilize strategic alliances as necessary. I refer to these alliances as “encouraging collaboration,” and believe that they complement in-house sales and development as an effective means of discovering new drugs and maximizing their value.

In the development of new drugs, our basic policy is to conduct development in-house to the establishment of POC (Proof of Concept: confirmation that the mechanism is effective and safe in humans). However, after the acquisition of POC, we carefully consider the features of each drug, and we examine a range of options to maximize the drug's value. In addition to in-house development and sales, we will aggressively implement joint development or license out a drug if we conclude that these methods would be effective.

According to this policy, we have focused our R&D resources on diabetes, which we have identified as a priority disease for our R&D initiatives. In addition, through the utilization of strategic alliances, we have worked to strengthen our R&D pipeline. Consequently, we increased the number of products in late-stage development, including the key development projects identified in the medium-term management plan. Currently, we believe that our R&D pipeline features top-level strengths in Japan, both quantitatively and qualitatively.

Drivers of Significant Growth

We are making steady progress with projects that we expect to contribute to results under the next medium-term management plan. In December 2009, Novartis Pharma filed NDAs in the U.S. and Europe for MS agent FTY720, which it licensed from the Company. Approval is expected in 2010. The number of MS patients worldwide is estimated to be about 2.5 million. Currently, MS drugs are used in injection formulations, and there is a lack of satisfactory treatments. FTY720 is an oral drug that shows great promise in regard to unmet needs for MS treatment, where treatments with greater efficacy and safety are needed. Patients and health care professionals have high expectations for this drug. I believe it has the potential to grow into a blockbuster product. In Japan, the Company and Novartis Pharma are moving ahead with co-development of FTY720, and we plan to file an NDA in 2010.

We also expect TA-7284 to become a major diabetes treatment agent. TA-7284 has an entirely different mechanism from conventional diabetes treatment agents, and we are moving forward with its development, targeting best in class. Overseas, Johnson & Johnson, which has licensed TA-7284 from Mitsubishi Tanabe Pharma, is conducting phase 3 trials. In Japan, the Company is moving forward with development. Phase 2 trials were commenced in November 2009.

As major new drugs discovered by the Company and sold around the world, each of these products will, I believe, have a major impact on our results under the next medium-term management plan.

Further, in January 2010 we signed an agreement with Mochida Pharmaceutical for the co-marketing in Japan of the antidepressant Escitalopram. We plan to file an NDA in fiscal 2010. The number of patients with depression in the domestic market is thought to exceed one million. Escitalopram is an SSRI (selective serotonin uptake inhibitor) that has already been launched in more than 90 countries and has been highly evaluated. It is a major drug, with global sales of about \$4.0 billion a year, and in Japan, Escitalopram is anticipated as another option in the pharmaceutical treatment of depression.

We are aiming to create new growth drivers and to become a global research-driven pharmaceutical company.

We will reform the Company, making it stronger and paving the way for continued growth in the years ahead.

We are also making favorable progress in the development of MP-424 and MP-513, which we expect to be launched. MP-424 is expected to be positioned as the gold standard in the treatment of chronic hepatitis C, while MP-513 is a diabetes treatment agent with a different mechanism of action from TA-7284.

To further bolster our R&D pipeline, in April 2010 we established the Clinical Incubation Department in the Development Division. In launching new drugs as rapidly as possible and maximizing their value, it is important to acquire POC quickly. Consequently, it is necessary to have an R&D road map that incorporates goals from basic research to clinical development. In accordance with that approach, we established the Clinical Incubation Department, which has overlapping responsibilities, in contrast to the previous system, where separate organizations were in charge of late research and early clinical development. Moving forward, we will continue working to become a global research-driven pharmaceutical company by working to increase the efficiency and speed of R&D activities and striving to discover new growth drivers.

Cultivating Corporate Culture

Since I was appointed president, I have stressed the importance of being an *inspiring company*. I believe that an *inspiring company* is one that fosters inspiration, pride, and affection among all employees, who work together to create the highest value and strive to continue to provide drugs that help society. To that end, it is important that we break away from past methods and concepts and that all employees have a broad perspective, acute sensitivity, and a strong action orientation. I will take the lead in fostering a free and open-minded corporate culture that will cultivate this type of employee. I will visit work sites throughout the Company and speak directly with employees, not only managers but also younger employees. In this way I will communicate my thoughts as an executive and directly experience the actual circumstances at our work sites. We are also moving ahead with reorganization initiatives. One example is the establishment of the Clinical Incubation Department, which was mentioned above. Our objective is to increase the efficiency and speed of our R&D activities. By removing the walls between research departments and development departments, we will advance cooperation among employees and foster opportunities for free and open discussions. In addition, we will activate the organization by providing employees in research departments and development departments with the chance to experience operations that they have not previously encountered.

By implementing a variety of reforms, including these restructuring initiatives, we will reform the Company, making it stronger and paving the way for continued growth in the years ahead. We will become a free and open, vibrant group. In this way, we will strive to be an *inspiring company* and to work toward our vision of being a global research-driven pharmaceutical company.



Basic Policy for the Return of Profits

The Company's basic policy on the distribution of earnings calls for providing a stable, ongoing distribution of earnings to shareholders while striving to maximize enterprise value by investing to bolster R&D and marketing activities from a medium-to-long-term perspective. For fiscal 2009, the Company set annual dividends at ¥28.0 per share, the same as in the previous year. The dividend payout ratio, calculated on the basis of net income less amortization of goodwill, was 39.0%.

In a difficult operating environment, we were unable to raise dividends for the year under review, but our objective for the dividend payout ratio is 35% before amortization of goodwill, and over the long term we will work to provide a return at a level that exceeds that objective. I would like to ask for the continued support of shareholders and other stakeholders.

August 2010

Michihiro Tsuchiya, Ph.D.
President & Representative Director, Chief Executive Officer

**Over the long term
we will work to provide
an increased return
to shareholders.**