Transcending Limits On Our Thoughts and Our Actions

We will be a company that continues to take on the challenge of change to achieve results.
Profit attributable to owners of the Company set a record high for the second consecutive year. We got off to a solid start in the first year of the current medium-term management plan.

The first year of Medium-Term Management Plan 16–20 has been completed. In fiscal 2016, revenue was down 0.4%, to ¥423.9 billion, core operating profit declined 11.7%, to ¥94.5 billion, and operating profit was up 15.0%, to ¥94.0 billion. Net profit attributable to owners of the Company increased 20.2%, to ¥71.2 billion.

Looking at the factors affecting revenue, an increase of 2.0% was recorded in revenue from domestic ethical drugs, which reached ¥314.2 billion. The NHI drug price revision implemented in April 2016 had the effect of reducing revenue by ¥17.0 billion. However, Simponi recorded substantial growth in revenue, and gains were also recorded by Tenelia, Talion, and other products. Revenue from priority products and vaccines was ¥185.9 billion in fiscal 2016, a year-on-year increase of ¥19.2 billion. As a result, we were able to record an increase in revenue from domestic ethical drugs.

On the other hand, royalty revenue, etc., declined 5.1%, to ¥82.2 billion. The Company recorded favorable growth in royalty revenue from Gilenya, which is licensed to Novartis International AG, of Switzerland. However, royalty revenue from Invokana and its fixed-dose combination with metformin, which are licensed to Janssen Pharmaceuticals, Inc., of the U.S. declined due to the effect of foreign exchange rates. In addition, non-recurring revenue, such as lump-sum payments from out-licensing, declined.

Revenue was down year on year, but the initial forecasts (announced May 11, 2016) called for revenue of ¥406.5 billion, so our revenue exceeded that forecast by a significant margin. The principal reason was better than expected results with domestic ethical drugs. In addition, operating profit and profit attributable to owners of the Company both increased. This was due principally to the gain in revenue and to the shift of certain R&D expenses to the next fiscal year. In addition, in the previous fiscal year we recorded restructuring expenses of ¥16.3 billion as non-recurring items. Consequently, profit attributable to owners of the Company set a record high for the second consecutive year. Overall, we got off to a solid start in the first year of the current medium-term management plan.

During the period covered by the current management plan, the business environment in Japan is expected to become more difficult due to the reevaluation of the NHI drug price system and to further progress in measures to promote the use of generics. In addition, royalty revenues from Gilenya are expected to decline as it goes off patent in the U.S., and accordingly we do not anticipate substantial growth in results. The period of the current medium-term management plan is positioned as a time for steadily maintaining revenue and gathering our strength in preparation for dramatic growth in fiscal 2020 and thereafter.

As milestones toward that objective, we set specific numerical objectives for each of the four strategic priorities for opening up the future under the current medium-term management plan. If we can achieve each of these objectives, I believe that we will build our strength and be able to record dramatic growth.

First, under Maximizing Pipeline Value, we have set a numerical objective of discovering 10 late-stage drug candidates during the period of the current medium-term management plan. In fiscal 2016 we made only a moderate degree of progress, with one drug candidate advancing to late-stage development. That was MT-2355 (expected indications: prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis, and Hib infection in infants).

However, in fiscal 2017 we plan to advance five drug candidates to late-stage development. I believe that fiscal 2017 will be a year of significant progress toward the achievement of our objectives, and at the same time a year of taking on challenges.
We were able to generate results, centered on autoimmune diseases as well as diabetes and kidney diseases, which are priority disease areas for our marketing activities.

In fiscal 2016, we were able to generate results, centered on autoimmune diseases as well as diabetes and kidney diseases, which are priority disease areas for our marketing activities. We have positioned the new drugs and priority products revenue ratio as a numerical objective, and this ratio reached 62% in fiscal 2016, compared with 55% in fiscal 2015. We are making progress in line with our plan, and in fiscal 2017 we expect this ratio to reach 70%.

In autoimmune diseases, in April 2016 we changed the Simponi sales framework with Janssen Pharmaceutical K.K. Previously, the two companies had implemented joint sales. After the change, however, Mitsubishi Tanabe Pharma is engaging in solo sales while conducting joint promotion with Janssen Pharmaceutical K.K.

In the treatment of Parkinson’s disease, as the disease progresses it is important to appropriately control the blood concentration of levodopa, a typical treatment agent. Through the use of its formulation technology, NeuroDerm Ltd. has achieved a world first with ND0612 through the successful creation of liquid formulations of levodopa and carbidopa, which are oral treatment agents. These formulations can be administered through subcutaneous injection in a sustained manner for 24 hours through the use of a mobile pump. In this way, the blood concentration of levodopa is controlled at a constant level, and this is expected to result in improvement in motor system symptoms, which are a problem for patients with advanced Parkinson’s disease.

NeuroDerm Ltd. is a pharmaceutical company that conducts research into new formulations of drugs for Parkinson’s disease and has strong technical development capabilities in the combination of drugs and devices. Currently, NeuroDerm Ltd. is advancing development of ND0612, a Parkinson’s disease treatment agent that has moved to phase 3 in the U.S. and Europe and is expected to be launched in fiscal 2019.

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Accelerating U.S. Business Development

We began sales of Radicava, the first new ALS treatment agent in the U.S. in 22 years. For patients in the U.S. and for the Company, this represents the fulfillment of a dream that we have had for 20 years.

In the U.S., we filed an application for MCI-186 (Japan product name: Radicut) for an indication of ALS in June 2016, and approval was received from the U.S. FDA in May 2017. In addition, we moved ahead with preparations for the start of sales, centered on Mitsubishi Tanabe Pharma America, Inc., a pharmaceutical sales company. In August 2017, we started sales under the product name Radicava.

This is the first new ALS treatment agent in the U.S. in 22 years, and we were strongly aware that patients were waiting for the launch of Radicava. Accordingly, we are very pleased that we were able to take this step forward. Moreover, we were finally able to produce results after many years of aiming to launch new drugs in the U.S. and continuing to take on a variety of challenges. For patients in the U.S. and for the Company, this represents the fulfillment of a dream that we have had for 20 years.

However, the start of sales is not the goal. What is important is that Radicava be delivered to patients and contribute to their treatment. Pharmaceutical accessibility—how to appropriately provide drugs to patients—has become a social issue, and I will make this issue my highest priority. In particular, Radicava, which requires intravenous (IV) administration at a medical facility, is a drug that places a comparatively high burden on ALS patients. Accordingly, providing support for accessibility is extremely important, and as the provider of this new drug we recognize that this is our obligation to society.

As one specific initiative, we established a patient support service called Searchlight Support and set up a portal website. This name incorporates the meaning of shining a light on patients. For example, through this website, we are implementing initiatives to reduce as much as possible the physical limitations and economic limitations faced by patients. For example, we are providing introductions to the medical institutions that can offer treatment in a manner that is most convenient for the patient, responding to questions about insurance coverage, and providing introductions to support programs for low-income patients. In addition, we are also actively offering support for academic conferences and patient organizations. I believe that working hard to implement these types of initiatives will support true contributions to the treatment of patients and will consequently lead to higher sales of Radicava.

We were able to make a major step forward toward the achievement of U.S. revenue of ¥80.0 billion. However, it will be difficult to achieve this objective with only Radicava. Accordingly, we have implemented initiatives to secure drug candidates and products that match our business strategies. As I mentioned, we reached agreement with NeuroDerm Ltd. regarding the start of sales for Canaglu (NHI drug price basis) surpassed ¥30.0 billion, and in fiscal 2017 we will aim for a further increase. This is a field in which competition is intense, and this is not an objective that will be easy to accomplish. The results will be determined in the second half of fiscal 2017. First, the Canaglu evidence has been strengthened by the results of the CANVAS trials, which were announced in June 2017. Furthermore, in July approval was received for Canalia Combination Tablets, Japan’s first combination drug that includes a DPP-4 inhibitor and an SGLT2 inhibitor. With this asset, we will work to achieve our fiscal 2017 objectives.

1. Ratio of revenue from new products and priority products to revenue from domestic ethical drugs
2. Large-scale clinical trials with approximately 10,000 participants to assess the safety of an SGLT2 inhibitor with regard to the cardiovascular system and kidneys, implemented by Janssen Pharmaceuticals, Inc., of the U.S.

In regard to specific initiatives for Strengthening IKUYAKU and Marketing, please refer to “Messages from the Executives Responsible for the Four Strategic Priorities” on page 24 and 25.
The launch of Radicava in the U.S. has been widely covered in the media, due in part to its impact as the first new ALS drug in 22 years. As a result, recognition of Mitsubishi Tanabe Pharma in the U.S. is increasing. This drug truly has value for patients and for the Company, and I want to ensure that we increase its sales in the U.S., contribute to many patients, and expand our U.S. business.

In regard to specific initiatives for Accelerating U.S. Business Development, please refer to “Messages from the Executives Responsible for the Four Strategic Priorities” on page 26.

Our objective is to reduce the total of cost of sales and SG&A expenses by ¥20.0 billion by fiscal 2020 (in comparison with fiscal 2015). In fiscal 2016, we achieved a reduction of ¥8.0 billion, and in fiscal 2017 we are forecasting that the amount of the reduction will reach ¥10.0 billion. We are making progress in line with our plan. In particular, we have steadily reduced the cost of sales, but I believe that the key to achieving our objectives will be further working-style reforms.

Currently, society is increasingly critical of long work hours, and there is a call for enhancing the quality of work without expanding the work hours. Accordingly, we must raise the productivity of each employee through working-style reforms.

We have implemented rigorous initiatives to increase productivity in plants, but I believe that there is still substantial room for improvement on a Companywide basis. First, we are establishing a range of measures so that employees, in the midst of their daily work activities, reevaluate work that has a low priority and work that will not lead to improvements in operational quality. For example, to reduce the volume of work at the head office, we have instituted a system under which employees leave the office at a fixed time each Friday. In addition, in the Sales and Marketing Division, we are taking steps to increase operational efficiency on the front lines by reducing across-the-board directions from the head office and delegating authority to branches. I have asked all employees to advance these types of initiatives while taking on the new tasks that we need to commence in order to achieve sustained growth.

In regard to specific initiatives for Reforming Operational Productivity, please refer to “Messages from the Executives Responsible for the Four Strategic Priorities” on page 27.

Under the current medium-term management plan, our key concept is to open up the future of “medicine” rather than “pharmaceuticals.” The reason we chose this key concept is that we are not simply providing a product in the form of pharmaceuticals. Rather, we are contributing to medicine, including through the provision of information related to appropriate usage, efficacy, and safety, and we want all officers and employees to be aware of this point of view.

In addition, I believe that pharmaceutical companies will not be able to survive in the future if they limit themselves to the traditional concept of pharmaceuticals. Currently, we are focusing on the establishment of an R&D system for the acquisition of POC in the U.S. As one facet of those initiatives, we are creating regular opportunities for the exchange of opinions between researchers in Japan and employees in the U.S. who are MDs. On the medical front lines in the U.S., there are unmet medical needs that are entirely different from those in Japan. In addition, I have personally been surprised many times at the extremely diverse range of ways in which diseases are approached in the U.S. I think that the traditional “pharmaceutical” framework will never generate these types of concepts. I want our researchers to experience the medical front lines in the U.S. and to take on the challenge of drug discovery from the higher viewpoint of “contributing to medicine” rather than simply “discovering drugs.”

In regard to specific initiatives for Reforming Operational Productivity, please refer to “Messages from the Executives Responsible for the Four Strategic Priorities” on page 27.
From the standpoint of marketing, the role of MRs is currently undergoing significant change. One is the urgent need to address digital marketing using ICT in a setting marked by limited opportunities to meet face to face with doctors. In fiscal 2016, we took steps to increase the use of our information website for health care professionals, and the number of new members recorded a significant gain. In regard to the role of MRs, we believe that the priority will shift from the simple provision of pharmaceutical information to the provision of information that health care professionals cannot obtain from this type of website when they are treating patients.

Next, progress is being made in the government-led move to establish comprehensive community care systems, and in this environment the importance of area marketing is increasing. In fiscal 2016, we established a foundation for area marketing by assigning area marketing planners to each sales office. To realize comprehensive community care systems, in addition to collaboration among stakeholders.

It will be increasingly necessary to strive to increase corporate value and secure the understanding of stakeholders.

There has been an increasingly clear trend toward the consideration of non-financial elements, such as ESG (Environment, Society, Governance), in making decisions about investing in companies. The MCHC Group, of which Mitsubishi Tanabe Pharma is a member, believes that, through our business activities, we must address environmental and social issues and contribute to increases in people’s health and the sustainability of society. Accordingly, the MCHC Group has established the KAITEKI concept and the MOS (Management of Sustainability) Indexes, which are KAITEKI indexes. The MOS indexes are divided into three groups—sustainability indexes, for contributions to the sustainability of the natural environment; health indexes, for contributions to people’s health; and comfort indexes, for contributions to people’s comfort.

In independently formulating and disclosing quantitative indexes regarding non-financial elements, the MCHC Group is ahead of the times, and this is a source of pride for us. It will be increasingly necessary to strive to increase corporate value and secure the understanding of stakeholders through these types of initiatives. Mitsubishi Tanabe Pharma is aggressively moving forward with initiatives related to ESG, and we are disclosing the details of these initiatives in a variety of ways, including on pages 53 to 70 of this report and on our CSR website. Future issues will include achieving wide-ranging recognition of these initiatives among stakeholders.

Among the MOS Indexes, we play a central role in contributing through the health indexes. In regard to the health indexes, quantitative objectives have been set for the categories of “contribute to medical treatment,” “contribute to improvements of QOL,” and “contribute to early detection and prevention of disease.” In fiscal 2016, we made steady progress in regard to these three quantitative objectives. Currently, elements related to product sales are a significant part of the basis for the calculation of these indexes, but moving forward I would like to see consideration given to incorporating the viewpoint of “contribute to medicine” into the indexes, such as initiatives related to medical accessibility, as discussed above.

To strengthen corporate governance, in June 2016 the Company established the Nomination Committee and the Compensation Committee as voluntary advisory committees under the Board of Directors. This step was taken to further enhance corporate governance by strengthening the independence, objectivity, and accountability of the functions of the Board of Directors with respect to the nomination and compensation of its executives. Each of these committees is chaired by an independent outside director and has independent officers as a majority of its members. Also, to enhance the effectiveness of the Board of Directors and increase corporate value, since fiscal 2015 we conduct evaluations of the effectiveness of the Board of Directors. In consideration of the results, we increased the number of outside directors by one director in June 2017. Furthermore, we introduced a performance-linked stock compensation plan that has both a high degree of linkage with the performance of the Company and high levels of medical facilities, it will also be necessary to enhance collaboration among people involved with patients, such as doctors, pharmacists, and care managers. I believe that one important role of MRs will be to support that collaboration and see that patients can receive the best treatment. In other words, MRs will work to enhance access to medical treatment in each region.

In this way, in the diverse venues in which we implement our business activities, we need to transcend the previous limits on our thoughts and our actions. Transcending limits on our thoughts refers to accepting diverse ways of thinking without being restricted by previous values and experience, leading to better proposals and decisions. Transcending limits on our actions refers to taking action to generate more-significant results, including not only internal limits but also building relationships outside the Company, including with other industries. With everyone at Mitsubishi Tanabe Pharma transcending limits on our thoughts and our actions, we can open up the future of medicine.
Message from the President

Our basic policy calls for providing a stable and continuous return to shareholders while striving to increase enterprise value by aggressively implementing strategic investment and R&D investment to achieve sustained growth.

Under the current medium-term management plan, we will work to enhance shareholder return, with a basic aim of a dividend payout ratio of 50%. In fiscal 2016, the Company achieved an increase in operating profit and set a new record high for profit attributable to owners of the Company. Consequently, in accordance with the basic policy on shareholder return, the Company set annual dividends at ¥52.0 per share, an increase of ¥6.0 per share. The dividend payout ratio was 40.9%, compared with 43.5% in the previous fiscal year.

In fiscal 2017, we are planning ordinary dividends of ¥56.0 per share, and to commemorate the 10th anniversary of the Company's founding on October 1, 2017, we plan to implement a commemorative dividend. Consequently, for fiscal 2017 we are planning annual dividends of ¥66.0 per share, and forecasting a consolidated dividend payout ratio of 51.8%.

Looking back at the Company’s progress to date, under Medium-Term Management Plan 08–10 we set an objective of sales of ¥50.0 billion for Remicade, which was our growth driver in the initial period after the Company's founding. However, we were able to grow Remicade to the point where sales surpassed ¥60.0 billion in the final fiscal year of the plan. Next, under Medium-Term Management Plan 11–15, we launched a number of new products that became our new growth drivers in Japan. Overseas, two products—Gilenya and Invokana—became major drugs, and the resulting royalty revenue became a pillar of our earnings. Under the current medium-term management plan, we have launched Radicava in the U.S., and we have made significant progress toward opening up doors for Accelerating U.S. Business Development, which is positioned as the next pillar of our earnings.

In this regard, I think that it is clear that Mitsubishi Tanabe Pharma is a company that can take on the challenge of change to achieve results. Moving forward, we will continue this progress and strive to transcend limits on our thoughts and our actions. In this way, we will continue to be a company that can take on the challenge of change to achieve results. I would like to ask our shareholders and investors for their support of Mitsubishi Tanabe Pharma in the years ahead.

September 2017
Masayuki Mitsuka
President & Representative Director

Shareholder Return

Under the current medium-term management plan, we will work to enhance shareholder return, with a basic aim of a dividend payout ratio of 50%. In addition, in fiscal 2017 the Company will mark the 10th anniversary of its founding, and we plan to implement a commemorative dividend.

Forecasts for Fiscal 2017 (Announced on May 10, 2017)

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<thead>
<tr>
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<th>Fiscal 2017 (forecasts)</th>
<th>Fiscal 2016</th>
<th>% Change</th>
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<tbody>
<tr>
<td>Revenue</td>
<td>¥441.0 billion</td>
<td>¥423.9 billion</td>
<td>+ 4.0%</td>
</tr>
<tr>
<td>Core operating profit</td>
<td>¥90.0 billion</td>
<td>¥94.5 billion</td>
<td>– 4.8%</td>
</tr>
<tr>
<td>Profit attributable to owners of the Company</td>
<td>¥71.5 billion</td>
<td>¥71.2 billion</td>
<td>+ 0.3%</td>
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For further information about KAITEKI and the MOS Indexes, please see the MCHC website.
http://www.mitsubishichem-hd.co.jp/english/kaiteki_management/
http://www.mitsubishichem-hd.co.jp/english/sustainability/mos/

For transparency and objectivity, the objective of the plan is to clarify the linkage between the compensation for directors and officers and the performance of the Group, and to share with the Company's shareholders not only the benefits of increases in the Company's stock price but also the risks associated with decreases, thereby boosting the motivation and morale of the directors for the sustainable growth of the Group and the expansion of corporate value over the medium- to long-term.

Future issues regarding the administration of meetings of the Board of Directors will include strengthening the function of monitoring our progress with business strategies, including the medium-term management plan. Another issue will be bolstering the function of rationally evaluating the suitability of such matters as large-scale investment projects that require rapid decisions. We are now conducting deliberations in regard to these issues.

For further information about KAITEKI and the MOS Indexes, please see the MCHC website.
http://www.mitsubishichem-hd.co.jp/english/kaiteki_management/
http://www.mitsubishichem-hd.co.jp/english/sustainability/mos/

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