Transcending Limits and Fully Achieving Our Goals to the End
Mitsubishi Tanabe Pharma Is Taking the Next Step
Overview of Fiscal 2017

Our revenue reached a record high due to growth in sales of fiscal 2017 priority products and to a major contribution from the launch of Radicava in the U.S. However, due to our aggressive strategic investment, we recorded declines in core operating profit, operating profit, and profit attributable to owners of the Company.

Mitsubishi Tanabe Pharma is currently implementing Medium-Term Management Plan 16–20: Open Up the Future, which was commenced in fiscal 2016. In fiscal 2017, the second year of the plan, we recorded revenue of ¥433.8 billion, up 2.3%; core operating profit of ¥78.5 billion, down 16.9%; operating profit of ¥77.2 billion, a decrease of 17.9%; and profit attributable to owners of the Company of ¥57.9 billion, a decline of 18.7%.

First, I will explain the factors affecting revenue. Domestic sales of ethical drugs decreased 1.5%, to ¥309.3 billion. Simponi, Tenelia, Canaglu, and other priority products registered growth, and excluding vaccines, revenue from fiscal 2017 priority products increased ¥7.4 billion year on year, to ¥154.4 billion. However, revenue from vaccines declined ¥3.8 billion, to ¥35.0 billion. Furthermore, revenue from long-listed drugs declined, and the transfer of the generic drugs business to Nipro in October 2017 had the effect of reducing revenue by ¥7.5 billion.

In royalty revenue, etc., we recorded growth in royalty revenue from Gilenya, which is licensed to Novartis, of Switzerland, but we registered a decline in royalty revenue from Invokana and its fixed-dose combination with metformin, which are licensed to Janssen Pharmaceuticals, of the U.S. As a result, royalty revenue, etc., declined 3.8% year on year, to ¥79.1 billion.

In this way, revenue from domestic ethical drugs and royalty revenue, etc., recorded declines. Nonetheless, revenue from overseas ethical drugs registered a significant increase, rising 70.0%, to ¥38.5 billion. The principal reason for this gain was the contribution made by Radicava, which was launched in the U.S. in August 2017. Radicava has gotten off to a strong start, with revenue of ¥12.3 billion in fiscal 2017.

As a result of the above factors, revenue reached a record high. However, SG&A expenses rose as a result of the launch of Radicava and other factors, and R&D expenses increased significantly due to development candidates moving to late-stage development and to the acquisition of NeuroDerm, of Israel. Due to this aggressive advancement of strategic investment, we recorded declines in core operating profit, operating profit, and profit attributable to owners of the Company.
In fiscal 2017, we were able to advance four drug candidates to late-stage development. We currently have five late-stage drug candidates, and our highest priority task is to launch these candidates as soon as possible.

During the period of the current medium-term management plan, the domestic business environment will become increasingly challenging, and royalty revenue from Gilenya is expected to decline as it goes off patent in the U.S. Accordingly, we do not anticipate substantial growth in our results. The period of the current medium-term management plan is positioned as a time for steadily securing revenue and gathering our strength in preparation for dramatic growth in fiscal 2020 and thereafter.

To that end, we have established four strategic priorities as milestones, and for each of these priorities we have formulated specific quantitative objectives. If we can achieve these objectives, I believe that we will be able to accumulate the strength that will drive dramatic growth.

First, in maximizing pipeline value, we will invest ¥400.0 billion in R&D expenses, centered on the priority disease areas of autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines. We have established a numerical target of 10 late-stage drug candidates.

In fiscal 2017, we were able to advance four drug candidates to late-stage development. We started late-stage clinical trials in Japan for MT-5547 (expected indication: osteoarthritis) in autoimmune diseases, MT-5458 (expected indication: renal anemia) in diabetes and kidney diseases; and MT-5199 (expected indication: tardive dyskinesia) in central nervous system diseases. In addition, in vaccines, in the U.S., Europe, and Canada, and other regions we started late-stage clinical trials for adults for MT-2217 (expected indication: prophylaxis of seasonal influenza).

As a result, together with MT-2355 (expected indications: prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis, and Hib infection in infants), a combined vaccine for five diseases that started late-stage clinical trials in Japan in fiscal 2016, we now have five late-stage drug candidates. Furthermore, we are preparing for late-stage clinical trials in the U.S. and Europe for ND0612 (expected indication: Parkinson's disease) from NeuroDerm, which we acquired in October 2017. In February 2018, we acquired Stelic Institute & Co., thereby strengthening our pipeline in the field of autoimmune diseases with the acquisition of a nucleic acid drug (STNM01) in the field of inflammatory bowel disease.

In this way, we have achieved a certain degree of success in advancing drug candidates, and our highest priority will be to launch late-stage drug candidates as rapidly as possible. Also, in regard to the overall composition of our pipeline, over the next two years the leading role in development will be shifted from Japan and Asia to a global basis. R&D expenses were ¥64.7 billion in fiscal 2016, the first year of the plan and ¥79.0 billion in fiscal 2017. We are forecasting R&D expenses of ¥84.5 billion in fiscal 2018.

We made generally favorable progress with each of our initiatives, but the NHl drug price revisions implemented in April 2018 will have a significant influence on the achievement of our fiscal 2020 revenue target.

In strengthening IKUYAKU and marketing, our target for revenue from domestic ethical drugs in fiscal 2020 is ¥300.0 billion. This target takes into account the revision of the NHl drug price system during the period covered by the current management plan as well as further market penetration by generic drugs. To sustain the current level of revenue, we will replace a large portion of our product portfolio and raise the new drugs and priority products revenue ratio1 from 55% in fiscal 2015 to 75% in fiscal 2020.

In autoimmune diseases, through a sales alliance with Janssen Pharmaceutical K.K., we are recording favorable growth in revenue from Simponi. The combined share of Remicade and Simponi in the market for biologics (see the “Explanation of Terms” section) used in the treatment of autoimmune diseases was approximately 37% in fiscal 2017. These drugs are maintaining a dominant position as the top brand. Furthermore, in May 2017 we commenced a sales alliance for Stelara, a treatment agent for Crohn's disease developed by Janssen Pharmaceutical K.K., and in June 2018 we concluded an agreement to update the sales framework. In these ways, with a lineup of biologics that includes Remicade, Simponi, and Stelara, I believe that we have further reinforced our strengths in the field of autoimmune diseases.

In diabetes and kidney diseases, Tenelia, a DPP-4 inhibitor, and Canagli, an SGLT2 inhibitor, are demonstrating synergies through a sales alliance with Daiichi Sankyo, and revenue from these products continues to increase. In addition, in September 2017 we launched a new product, Canalia. This is Japan's first combination drug that includes a DPP-4 inhibitor and an SGLT2 inhibitor. We are also marketing Canalia through a sales alliance with Daiichi Sankyo and it has gotten off to a smooth start.

Furthermore, in central nervous system diseases, Lexapro is recording solid growth. In addition, in vaccines, the Company and The Research Foundation for Microbial Diseases of Osaka University
established BIKEN Co., a joint venture for vaccine manufacturing that began operations in September 2017. In this way, the Company and the research foundation will aim to achieve a more stable supply and increase production of vaccines by combining our pharmaceutical production-related systems and management methods and accelerating the reinforcement of our production foundation.

As a result of these initiatives, the total revenue from fiscal 2017 priority products and vaccines increased 1.9%, to ¥189.4 billion, and the new drugs and priority products revenue ratio was 63%.

In this way, we have made generally favorable progress with each of the initiatives that we have implemented to strengthen IKUYAKU and marketing. However, the NHI drug price revisions implemented in April 2018 will have a significant influence on the achievement of our fiscal 2020 revenue target of ¥300.0 billion. When we formulated the current plan, we anticipated the NHI drug price revision, but the details of the revision are more severe than we envisioned. Basically, we cannot expect future growth of the domestic ethical drug market.

During the period covered by the current plan, it will be difficult to follow up Canalia with the launch in Japan of a product developed in-house. However, in November 2017 we commenced a sales alliance for Rupafin, an anti-allergy agent discovered by Teikoku Seiyaku. In a range of disease areas, by aggressively pursuing opportunities for sales alliances with other companies in this way, we will work to enhance domestic sales and make progress toward the achievement of our numerical targets.

1. Ratio of revenue from new products and priority products to revenue from domestic ethical drugs.

Accelerating U.S. Business Development

Through the launch of Radicava, we were able to open a door to the future. To achieve our U.S. revenue target of ¥80.0 billion, as well as subsequent growth in the years ahead, we must open the second and third doors.

In accelerating U.S. business development, we have set a numerical target of ¥80.0 billion in U.S. revenue in fiscal 2020. In addition, to establish our business foundation in the U.S., we plan to implement strategic investment of more than ¥200.0 billion over the period of the current medium-term management plan.

Fiscal 2017 was a year in which we took a big step forward in our U.S. business. MCI-186 (Japan product name: Radicut) received approval in the U.S. in May 2017 for an indication of ALS, and sales were started in August under the product name Radicava. As I mentioned, Radicava has gotten off to a strong start, and by the end of August 2018 the number of patients treated with Radicava had surpassed 3,000. Moving forward, in addition to the treatment of new patients, we will also leverage Searchlight Support and focus on initiatives to increase the treatment continuation rate. As a result of these initiatives, we are forecasting fiscal 2018 revenue of ¥31.5 billion, more than 2.5 times the level in fiscal 2017. For many years, we continued to take on challenges with the aim of launching new drugs in the U.S. With the launch of Radicava, I believe that we have achieved that objective and opened a door to the future.

However, this is only the first step. Realizing the achievement of our U.S. revenue target of ¥80.0 billion, as well as subsequent growth, we must open the second and third doors. One key will be MT-2271 and other plant-based Virus-Like Particle (VLP) vaccines, which are being developed by Group subsidiary Medicago, of Canada. If MT-2271 makes favorable progress, we expect to file applications in North America within fiscal 2018 for the prophylaxis of seasonal influenza, and we anticipate the acquisition of approval in fiscal 2019. In addition, to enhance the product value, we will move forward with development initiatives for applications for children and the elderly. Moreover, to expand the business after the launch, we also plan to start construction of a full-scale manufacturing facility for plant-based VLP vaccines in Quebec, Canada.

Another key will be NeuroDerm. NeuroDerm has a pipeline that includes ND0612 and other drugs for central nervous system diseases, such as Parkinson’s disease. Through combinations of formulation technologies and devices, NeuroDerm is advancing the development of innovative drugs that address unmet medical needs. Up to this point, we have implemented strategic investments totaling approximately ¥120.0 billion, such as the acquisition of NeuroDerm. Moving forward, we will further advance investment to strengthen our business in the fields of neurological disorders and vaccines, and will search for new disease areas that have a high degree of synergy with existing areas.

In addition, we also intend to roll-out Radicava, MT-2271, and ND0612 in other markets, including Europe. We are already making progress on these initiatives. For Radicava, we filed applications in Switzerland in December 2017, Canada in April 2018, and Europe in May 2018. We will also consider initiatives in the ASEAN region and other markets.

We have started full-fledged business initiatives in the U.S., which is the world’s largest pharmaceutical market. To develop these operations into our second pillar of business after Japan, we will continue to move forward without slackening our efforts.

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Reforming Operational Productivity

We are making strong progress, but the business environment in the domestic ethical drugs market is increasingly challenging, and there is a growing sense of uncertainty about the future. In this setting, we will implement initiatives that aim one level higher.

In reforming operational productivity, we have set numerical targets of reducing the total of cost of sales and SG&A expenses by ¥20.0 billion in comparison with fiscal 2015 by fiscal 2020 and of having a domestic workforce of less than 5,000 employees on a consolidated basis. In fiscal 2017, our initiatives were centered on controlling labor costs by optimizing the workforce and reducing procurement costs for active pharmaceutical ingredients and other items. As a result, we were able to reduce cost of sales by ¥3.0 billion and SG&A expenses by ¥3.0 billion. Consequently, the total of cost of sales and SG&A expenses was reduced by ¥14.0 billion in comparison with fiscal 2015, substantially exceeding the fiscal 2017 plan of ¥10.0 billion in reductions. In fiscal 2018, we expect to achieve ¥19.0 billion in reductions. In addition, the domestic consolidated workforce was 5,158 employees as of the end of fiscal 2017. Accordingly, we expect to achieve our numerical targets ahead of schedule.

In these ways, we are making strong progress in our initiatives in the area of reforming operational productivity. However, the business environment in the domestic ethical drugs market is increasingly challenging, and there is a growing sense of uncertainty about the future. In this setting, we will implement initiatives that aim one level higher. To that end, we have two key phrases. The first is leading-edge “digital technologies,” such as robotic process automation (RPA). The second is business “sharing,” including sharing within the same industry and with other industries. To fully leverage these key phrases, we will strive to consider all possibilities, foster working-style reforms, and secure resources for investment in future growth.

Working to Resolve Social Issues

Mitsubishi Tanabe Pharma wants to be a company that continues to provide value to important stakeholders—including patients, society, and employees.

There is a clear trend toward the consideration of non-financial elements, such as ESG (Environment, Society, Governance), in making decisions about investing in companies. In addition, there is growing interest in the Sustainable Development Goals (SDGs) that were adopted by the United Nations in 2015, and corporate activities that support the resolution of social issues are increasingly important.

Mitsubishi Tanabe Pharma wants to be a company that continues to provide value to important stakeholders—including patients, society, and employees—through its business activities.

In particular, we want to do more for patients than just helping in the treatment of diseases through the provision of pharmaceuticals. We want to contribute to health from a wide-ranging viewpoint. This includes helping people to restore their ability to enjoy daily life and to enjoy dynamic lifestyles in society as they look forward to bright futures. To assist as many people as possible in this way, Mitsubishi Tanabe Pharma will strive to open up the future of medicine.

Furthermore, 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 this way, we are evaluating the extent of contributions to sustainability.

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” (see the “Explanation of Terms” section), and “contribute to early detection and prevention of disease.” Currently, elements related to product sales are a significant part of the basis for the calculation of these indexes. It is difficult to evaluate the resolution of social issues simply by considering sales of pharmaceuticals. Moving forward, we will strive to increase corporate value by clarifying what we consider to be important social issues (material issues) and by incorporating the SDGs adopted by the United Nations.

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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/
Corporate Governance

As we accelerate our strategic investment initiatives, our three outside directors offer extremely valuable opinions in regard to investment decisions.

To strengthen corporate governance, we have steadily advanced measures from a variety of perspectives since we introduced outside directors in 2011. These measures have included increasing the number of outside directors, implementing evaluations of the effectiveness of the Board of Directors, establishing the Compensation Committee and the Nomination Committee, and introducing a performance-linked stock compensation plan. In particular, as we accelerate our strategic investment initiatives, our three outside directors offer extremely valuable opinions in regard to investment decisions. Each outside director actively participates in meetings of the Board of Directors, and we are receiving advice from their wide-ranging perspectives, backed by their extensive experience and knowledge as corporate executives.

On the other hand, we recognize that we will need to enhance diversity in regard to the operation of the Board of Directors. Currently, we have three outside directors, each of whom is from a different industry. In addition, our outside corporate auditors include specialists in law and finance. In these ways, the composition of our Directors and Corporate Auditors reflects consideration for diversity. However, in consideration of demands from the capital markets, I believe that we also need to increase diversity from the perspectives of gender and nationality. We must also consider how the composition of our Directors and Executive Officers will lead to the reinforcement of our corporate governance, and then move to the stage of implementation.

Shareholder Return

In fiscal 2017, looking at our results, we recorded declines in core operating profit, operating profit, and profit attributable to owners of the Company. However, we set annual dividends at ¥56.0 per share, an increase of ¥4.0 per share (not including the commemorative dividend). Including the commemorative dividend, the annual dividend was ¥66.0 per share, and the dividend payout ratio was 63.9%, compared with 40.9% in the previous fiscal year.

In fiscal 2018, due to the NHl drug price revision in Japan and to measures to promote the use of generics and biosimilars, our operating environment will become more challenging. Nonetheless, we will step up initiatives to bolster sales of fiscal 2018 priority products and to increase sales of Radicava in the U.S. Accordingly, we are forecasting increased revenue for fiscal 2018. However, targeting strong growth in fiscal 2020 and subsequent years, we will accelerate R&D investment in late-stage drug candidates, resulting in a record-high level of R&D expenses in fiscal 2018. Accordingly, in profits we anticipate continued declines in core operating profit, operating profit, and profit attributable to owners of the Company. In accordance with these results forecasts and the dividend policy, the Company plans to pay annual dividends for fiscal 2018 of ¥56.0 per share, the same as in the previous fiscal year (excluding the commemorative dividend), for a consolidated dividend payout ratio of 66.8% under IFRS.

Dividends

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<th>Dividends</th>
<th>Fiscal 2017</th>
<th>Fiscal 2018 (forecast)</th>
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<tbody>
<tr>
<td>Dividends per share (excluding commemorative dividend)</td>
<td>¥56</td>
<td>¥56</td>
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<tr>
<td>Commemorative dividend per share</td>
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<tr>
<td>Dividend payout ratio</td>
<td>63.9%</td>
<td>66.8%</td>
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Note: In commemoration of the 10th anniversary of its founding, the Company implemented a commemorative dividend of ¥10 per share in fiscal 2017.

Looking Ahead to the Next 10 Years

Looking ahead to the next 10 years and beyond, everyone at Mitsubishi Tanabe Pharma will work together to “transcend limits” and “fully achieve our goals to the end.” In this way, we will take the next step.

Mitsubishi Tanabe Pharma reached the 10th anniversary of its founding in 2017. During 2017, in accelerating U.S. business development, which is positioned as our greatest challenge under the current medium-term management plan, we were able to achieve our longstanding goal of launching a new drug in the U.S. and to open a door to the future. I believe that we made a strong start for the next 10 years. As I explained, we are also making overall progress in line with our plans for the other three strategic priorities.

However, our operating environment is undergoing dramatic change. In Japan, the effect on the Company of the April 2018 NHl drug price revision will be greater than expected. Moreover, in overseas operations, royalty revenue, etc., has been the driver of the Company’s revenue over the past several years, but intensified
competition has reduced the earnings power of Invokana, and royalty revenue, etc., is not expected to reach the planned level.

In consideration of this situation, we recognize that we will need to implement additional measures moving forward. However, we will not be able to take the next step if we limit ourselves to traditional working styles and to simply extend existing concepts. For example, in the U.S., Radicava has already opened one door, and the advanced technologies of Medicago and NeuroDerm are about to open other doors. But in the world beyond those doors, the functions and knowledge that Mitsubishi Tanabe Pharma has cultivated to date will not be sufficient. In other words, we must cultivate new capabilities.

To that end, we need to take on the challenge of new initiatives that transcend limits without being restricted by previous values and experience. Furthermore, we need to do more than just “take action” in a vague manner. We need to “fully achieve our goals to the end.” I believe that this approach will foster innovation and lead to growth that opens doors to the future, as individuals and as organizations. Looking ahead to the next 10 years and beyond, everyone at Mitsubishi Tanabe Pharma will work together to “transcend limits” and “fully achieve our goals to the end.”

In this way, we will take the next step. I would like to ask our shareholders and investors for their support of Mitsubishi Tanabe Pharma in the years ahead.

### Fiscal 2018 Results Forecast

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<tr>
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<th>Fiscal 2017</th>
<th>Fiscal 2018 (forecast)</th>
<th>% change</th>
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<tr>
<td>Revenue</td>
<td>¥433.8 billion</td>
<td>¥435.0 billion</td>
<td>+0.3%</td>
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<tr>
<td>Core operating profit</td>
<td>¥78.5 billion</td>
<td>¥70.0 billion</td>
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<td>Profit attributable to owners of the Company</td>
<td>¥57.9 billion</td>
<td>¥47.0 billion</td>
<td>–18.9%</td>
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September 2018

Masayuki Mitsuka
President & Representative Director

Mitsubishi Tanabe Pharma Corporate Report 2018 21