This section explains the business strategies that play the central role in initiatives to create value.
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-6548 (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 NH1 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 NH1 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 ratio\(^1\) 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 Canaglu, 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.

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

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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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.
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.
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.

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 NHI 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

<table>
<thead>
<tr>
<th></th>
<th>Fiscal 2017</th>
<th>Fiscal 2018 (forecast)</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>¥433.8 billion</td>
<td>¥435.0 billion</td>
<td>+0.3%</td>
</tr>
<tr>
<td>Core operating profit</td>
<td>¥78.5 billion</td>
<td>¥70.0 billion</td>
<td>−10.9%</td>
</tr>
<tr>
<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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</table>

September 2018

Masayuki Mitsuka
President & Representative Director
Basic Policy
Mitsubishi Tanabe Pharma strives to continually discover new drugs that address unmet medical needs around the world. The Company’s four priority disease areas are autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines. Centered on these areas, we are aiming to become a “pharmaceutical company that works with a sense of speed and is the first to deliver original value.” On that basis, we are focusing on the discovery of new drugs. Moreover, as we move forward we will expand discovery resources by aggressively leveraging open shared business through the in-licensing of discovery seeds as well as collaboration with other companies. We will also utilize the optimal discovery and development methods for each candidate, thereby shortening the period required until acquisition of POC (see the “Explanation of Terms” section).

Fiscal 2017 Initiatives
In fiscal 2017, we aimed for rapidly obtain POC for drug candidates, and focused on initiatives to promote the continued discovery of new drug candidates in the future. We reviewed the allocation of resources to discovery projects, from initial exploratory trials to late pre-clinical trials, and implemented the principles of selection and concentration. In addition, to achieve further gains in the quality and quantity of drug candidates that have newly entered clinical trials, we actively strengthened translational research, which involves the connection from pre-clinical trials to clinical trials.

As a result of these initiatives, in line with our plans, we initiated clinical trials to obtain POC in the U.S. and Europe for multiple drug candidates, such as MT-8554 (expected indications: vasomotor symptoms associated with menopause, etc.) and MT-7117 (expected indication: erythropoietic protoporphyria). We also made progress with the follow ups to those candidates. We are also conducting clinical trials for drug candidates in early stages, such as MT-4129 (expected indications: cardiovascular system, etc.), MT-0814 (expected indications: ophthalmologicals), and MT-2990 (expected indications: inflammatory diseases, autoimmune diseases, etc.). We are moving ahead with the expansion of drug discovery modalities for drug candidates.

1. Research conducted with the objective of applying the results of basic research to clinical trials and on the medical front lines.
2. Physical classification of treatment agents. Treatment methods, such as small molecule compounds; protein drugs, including peptide (middle molecule) drugs and therapeutic antibodies; nucleic acid drugs; cell therapy drugs; and regenerative medicine.
This section explains our initiatives in the area of business processes leading to product launch, from clinical research and basic research to the identification of candidate compounds (discovery seeds) that will become pharmaceuticals and the demonstration of superior medical value through the conduct of a variety of pre-clinical trials and clinical trials.

### Fiscal 2017 Results and Fiscal 2018 Initiatives

<table>
<thead>
<tr>
<th>Product</th>
<th>Fiscal 2017 Results</th>
<th>Fiscal 2018 Initiatives</th>
</tr>
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<tbody>
<tr>
<td><strong>Autoimmune Diseases</strong></td>
<td></td>
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<tr>
<td>MT-1303 (S1P receptor functional antagonist)</td>
<td>Reevaluated the development plan for in-house development</td>
<td>Promotion of activities for cooperation with other companies</td>
</tr>
<tr>
<td>MT-5547 (anti-NGF antibody)</td>
<td>Phase 2/3 trials initiated in Japan for osteoarthritis</td>
<td>Promotion of Phase 2/3</td>
</tr>
<tr>
<td>MT-7117 (dermatologicals, etc.)</td>
<td>Phase 1 completed</td>
<td>Phase 2 initiated overseas Plan to achieve POC</td>
</tr>
<tr>
<td>MT-2990 (inflammation, autoimmune diseases, etc.)</td>
<td>Phase 1 initiated</td>
<td>Phase 2 initiated overseas Plan to achieve POC</td>
</tr>
<tr>
<td><strong>Diabetes and Kidney Diseases</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MT-6548 (HIF-PH inhibitor)</td>
<td>Phase 3 initiated in Japan for renal anemia</td>
<td>Promotion of phase 3 (Targeting approval in fiscal 2020)</td>
</tr>
<tr>
<td>TA-7284 (SGLT2 inhibitor)</td>
<td>Promoted global clinical trial (CREDENCE study) in Japan, the U.S., Europe, etc., for diabetic nephropathy * Clinical trial client: Janssen Research &amp; Development</td>
<td>Targeting end of CREDENCE study in June 2019 Under consideration for acquisition of approval for diabetic nephropathy</td>
</tr>
<tr>
<td>MT-3995 (selective mineralocorticoid receptor antagonist)</td>
<td>Promoted phase 2 in Japan, with a focus on NASH (non-alcoholic steatohepatitis)</td>
<td>Promotion of activities for cooperation with other companies</td>
</tr>
<tr>
<td><strong>Central Nervous System Diseases</strong></td>
<td></td>
<td></td>
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<tr>
<td>MT-5199 (VMAT2 inhibitor)</td>
<td>Phase 2/3 initiated in Japan for tardive dyskinesia</td>
<td>Promotion of phase 2/3 (Targeting approval in fiscal 2021)</td>
</tr>
<tr>
<td>MT-8554 (nervous system, etc.)</td>
<td>Phase 2 initiated for painful diabetic peripheral neuropathy in the EU and for vasomotor symptoms associated with menopause in the U.S.</td>
<td>Promotion of phase 2 Targeting acquisition of POC in third quarter of fiscal 2018</td>
</tr>
<tr>
<td>ND0612 (levodopa / carbidopa)</td>
<td>NeuroDerm became wholly owned subsidiary (October 2017) Promoted long-term safety study</td>
<td>Phase 3 initiated in the U.S. and Europe for Parkinson’s</td>
</tr>
<tr>
<td>MT-1186 (edaravone / new administration route)</td>
<td>Considered new dosage form with the aim of increasing convenience for ALS patients</td>
<td>Phase 1 initiated</td>
</tr>
<tr>
<td><strong>Vaccines</strong></td>
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<tr>
<td>MT-2355 (combined vaccine for five diseases)</td>
<td>Promoted phase 3 in Japan</td>
<td>Promotion of phase 3</td>
</tr>
<tr>
<td>MT-2271 (plant-based VLP vaccine)</td>
<td>Initiated phase 3 (for adults) in the U.S., Europe, Canada, etc., for seasonal influenza</td>
<td>Filing in North America in fiscal 2018 (Targeting approval in fiscal 2019)</td>
</tr>
</tbody>
</table>
Since joining the Company, I have worked in discovery research, centered on physical property analysis of new drug candidate compounds. For the first two years, I worked with small-molecule pharmaceuticals, and since that time I have been working with biologics. For biologics, the manufacturing process is complex, and in addition to efficacy and safety, it is difficult to identify substances that are appropriate for manufacturing other than small-molecule pharmaceuticals. In this setting, it is my job as a researcher to use a variety of analyses to discover new drug candidate substances that proceed to clinical trials.

In 2017, I had the opportunity to visit Tanabe Research Laboratories U.S.A., in the U.S., and for about six months, I was able to gain experience on the front lines of discovery research. We have taken steps to build that type of system in cooperation with our pharmaceutical development subsidiaries in the U.S. (Mitsubishi Tanabe Pharma Development America) and Europe (Mitsubishi Tanabe Pharma Europe). We have strengthened the functioning of our drug discovery system, which is integrated from pre-clinical trials to acquisition of POC, and expect to see results from these initiatives in fiscal 2018.

Our basic policy is to utilize alliances with academia for basic research activities, such as identifying discovery targets and acquiring new technologies, as well as alliances with venture companies and other pharmaceutical companies for the acquisition of new drug discovery projects and joint research. In addition, drug discovery research for new modality is an area of special focus. We are working together with multiple partners, such as academic institutions and venture companies, to implement initiatives in this area while advancing the formation of a drug discovery ecosystem.

As one part of those initiatives, in fiscal 2017 three companies—Astellas Pharma, Daiichi Sankyo, and Mitsubishi Tanabe Pharma—cooperated in the launch of a new drug discovery program called JOINUS. Through this project, the partners will build a
drug repositioning library comprising compounds for which development was halted after the implementation of clinical trials or pre-clinical trials. We will provide this library to domestic research institutions selected for this program, and they will make evaluations using their own in vitro assays. In this way, we will aim to foster drug discovery projects that individual companies would not be able to come up with on their own.

As another initiative to establish the drug discovery ecosystem, we participated in the launch of the Immune-Mediated Inflammatory Diseases Consortium for Drug Development with the objective of promoting discovery research targeting immune-mediated inflammatory diseases. The participants in this consortium include three academic institutions, Keio University, Kochi University, and the National Institutes of Biomedical Innovation, Health and Nutrition, as well as three pharmaceutical companies, Mitsubishi Tanabe Pharma, Daiichi Sankyo, and Ono Pharmaceutical. A high-quality database will be constructed based on the various data accumulated by the consortium, and this database will be shared by the participating academic institutions and pharmaceutical companies. The pharmaceutical companies will be able to use this database in their own discovery research. On the other hand, the participating academic institutions will be able to use the database in order to make further progress with basic and applied research. Through the use of this unique new concept for industry–academia cooperation, we will aim to establish a new drug discovery ecosystem for the treatment of immune-mediated inflammatory diseases and the discovery of innovative drugs.

3. System to increase efficiency in the discovery process.
4. Testing in which drug reactions are detected in an artificial environment similar to that in the living organism, using human or animal tissue in test tubes, culture vessels, etc.

Outlook for Fiscal 2018 and Thereafter

The operating environment for pharmaceutical companies is undergoing dynamic change. In this setting, the Company must continuously launch innovative drugs. The “Sohyaku, Innovative Research Division” employees will strive to transcend previous frameworks and to become a standard-bearer for reforms. At the same time, the entire division will work to implement future-oriented reforms while maintaining a focus on results. In this way, we will aim for a system that can continually discover pharmaceuticals with true value. We will form a drug discovery ecosystem comprising the best partners. This initiative will include partners inside and outside of the Group as well as those in Japan and overseas. We will aggressively leverage a variety of drug discovery opportunities, build a global R&D system, and strive to achieve steady results in fiscal 2018 and thereafter.
Basic Policy

Mitsubishi Tanabe Pharma is strengthening its initiatives to maximize product value as rapidly as possible, centered on our priority disease areas—autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines. In addition, to strengthen our sales promotion activities we are further enhancing our special expertise in our priority disease areas, and are also promoting area marketing and digital marketing.

IKUYAKU

Fiscal 2017 Initiatives

Since April 2017, the “Ikuyaku. Integrated Value Development Division” has been responsible for operations from late-stage development through to post-launch activities. These operations are handled through the clinical research & development, medical affairs, and pharmacovigilance sections.

In Japan, we commenced late-stage development of three candidates—MT-5199 (expected indication: tardive dyskinesia), MT-5547 (expected indication: osteoarthritis), and MT-6548 (expected indication: renal anemia). For products that have already been launched, such as Canaglu and Tenelia, we worked to enhance product information. In addition, looking overseas we established a global pharmacovigilance system accompanying the start of overseas sales activities for Radicava, an ALS treatment agent that originated in-house.

Outlook for Fiscal 2018 and Thereafter

In fiscal 2018, in Japan, in addition to the abovementioned MT-5199, MT-5547, and MT-6548, we will advance the clinical trial for MT-2355, a combined vaccine for five diseases. In addition, we will aim for an additional indication of diabetic nephropathy for Canaglu. For each of these products, we will strive to advance clinical trials while maintaining quality without losing speed. Currently, after the implementation of POC trials overseas for two compounds that originated in-house—MT-7117 (expected indication: erythropoietic protoporphyria) and MT-8554 (expected indications: painful diabetic peripheral neuropathy, and vasomotor symptoms associated with menopause)—we plan to advance development in Japan as well. Moreover, clinical trials in China for MP-513 (teneliglitin), a diabetes treatment agent originated in-house, have reached phase 3, and we expect MP-513 to contribute to our China business in the future.
This section explains our initiatives in post-marketing business processes, such as sales promotion activities by the MRs and life-cycle management to increase product value.

The medical affairs sections have a special focus on activities to increase product value after launch. For our priority products, such as Remicade, Canaglu, Tenelia, and Canalia, we will further clarify the product profile through the use of overseas information and post-marketing clinical trials (safety and efficacy). In this way, we will make it easy to understand the positioning of our products in treatment. On the other hand, the pharmacovigilance sections collect safety information and clarify in-depth product safety profiles. Moving forward, we will continue working to develop the capabilities of our staff members so that they improve the knowledge required to engage in disease-related discussions with health care professionals, and will work to further enhance their understanding of product safety. Also, in collaboration with the medical affairs sections, for Canaglu and other products, we are reporting data regarding clinical safety in Japanese patients at academic conferences, etc., and moving forward we intend to continue to actively communicate with healthcare professionals regarding safety information.

Since the Ikuyaku, Integrated Value Development Division was established, through collaboration among the clinical research & development sections, which develop products; the pharmacovigilance sections, which work to thoroughly understand safety; and the medical affairs sections, which provide scientific, well-balanced explanations of efficacy and safety, we have been working to increase product value and communicate information about our products to related parties. Currently, we are further advancing this initiative. We will strive to build a system that can provide information in a more effective and efficient manner from an earlier phase, i.e., from the late-stage development phase. In this way, we will work to support the use in patient treatment of highly anticipated new drugs for which launches are planned.

Advancing New Drug Development and Life-Cycle Management Strategy

In fiscal 2017, we made progress with initiatives to maximize the value of drugs, as follows.

Acquisition of Approval

- **Remicade**
  Approval was received for a partial change in administration / dosage (shortened administration interval) for Crohn's disease in Japan.

- **MT-2412**
  Approval was received for type 2 diabetes mellitus in Japan (launched under the product name Canalia).

- **MCI-186 (Japan product name: Radicava)**
  Approval was received for ALS in the U.S. (launched under the product name Radicava).

- **Novastan**
  Approval was received for acute cerebral thrombosis in China.
  Note: In June 2018, Jubila was approved for tinea unguium in Taiwan.

Application Filed

- **TA-7284 (Japan product name: Canaglu)**
  An application was filed in Indonesia for type 2 diabetes mellitus.

- **MP-214**
  An application was filed in South Korea and Taiwan for schizophrenia.
  Note: An application for MP-214 for schizophrenia was filed in Singapore in June 2018.

- **MCI-186 (Japan product name: Radicava)**
  An application was filed in Switzerland for ALS.
  Note: For MCI-186, applications were filed for ALS in Canada in April 2018 and in Europe in May 2018.

Out-Licensed Products

- **Valixa**
  An application was filed in Japan for the prevention of cytomegalovirus disease in pediatric organ transplant patients.

- **FTY720 (product name: Gilenya)**
  Licensee Novartis, of Switzerland, filed applications for pediatric multiple sclerosis in the U.S. and Europe.
  Note: In May 2018, approval was received in the U.S. for FTY720 for pediatric multiple sclerosis.

- **TA-7284 (product name: Invokana)**
  Licensee Janssen Pharmaceuticals, of the U.S., filed applications in the U.S. and Europe for reduction of the risk of cardiovascular death in type 2 diabetes patients at risk for or with a history of cardiovascular disease (CANVAS/CANVAS-R).

- **MT-210**
  Licensee Minerva Neurosciences, of the U.S., started phase 3 clinical trials for schizophrenia in the U.S. and Europe.

- **MT-4580**
  Licensee Kyowa Hakko Kirin obtained approval in Japan for secondary hyperparathyroidism in patients on maintenance dialysis. In addition, phase 3 clinical trials were started in Japan for an indication of hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism.
utilizing real and digital initiatives, such as making prescription proposals in face-to-face meetings with health care professionals while also operating exclusive websites for those professionals.

**Initiatives Centered on Priority Disease Areas**

In the field of autoimmune diseases, Janssen Pharmaceutical K.K. obtained approval of an indication of Crohn’s disease for Stelara, and in May 2017 Mitsubishi Tanabe Pharma and Janssen Pharmaceutical K.K. started co-promotion. Sales are handled by Janssen Pharmaceutical K.K., and the provision of information to health care professionals is implemented jointly by both companies. Up to this point, Mitsubishi Tanabe Pharma has sold Remicade as a treatment agent for Crohn’s disease. Moving forward, we will also conduct information provision activities for Stelara, which has a different mechanism of action. In this way, the Company is now able to provide a new treatment option for patient’s with Crohn’s disease.

In addition, Mitsubishi Tanabe Pharma now offers Remicade, Simponi, and Stelara, making us the only pharmaceutical company that offers three biologics in this field. We have received high evaluations from health care professionals as a pharmaceutical company that can provide the optimal treatment option to many patients who are suffering from autoimmune diseases, and as a pioneer in biologics. In fiscal 2017 our share of the market for biologics used to treat autoimmune diseases was 37%, and we have established a position as a leading brand in this market. Janssen Pharmaceutical K.K. received approval for an additional indication of ulcerative colitis in March 2017, and in fiscal 2017, the first year, Simponi earned a share of 10% of the market for ulcerative colitis. In this way, Simponi has gotten off to a favorable start.

Next, in the field of diabetes, the demand for combination tablets is increasing due to the need to control health care expenditures and address the harmful effects of polypharmacy and other health care issues. In this setting, in September 2017 we were able to launch Canalia, a type 2 diabetes mellitus treatment agent, as Japan’s first combination drug that includes a DPP-4 inhibitor and an SGLT2 inhibitor. Canalia has gotten off to a favorable start, and we are demonstrating synergies resulting from our ability to offer three diabetes treatment agents—Tenelia, Canaglu, and Canalia.

In vaccines, the operating environment is undergoing drastic change, and we are moving ahead with the establishment of a system that facilitates the realization of a stable vaccine supply. In fiscal 2017, there was concern about a shortage of influenza vaccine in Japan, and we worked to offer a stable supply in order to avoid any disorder in the market. As a result, we were able to maintain the No. 1 share among sales companies in the domestic market. The Research Foundation for Microbial Diseases of Osaka University (BIKEN Foundation) and Mitsubishi Tanabe Pharma established Biken Co., a joint venture for vaccine manufacturing that began operations in September 2017.

In addition, in November 2017 the Company and Teikoku Seiyaku, began co-promotion of Rupafin, an anti-allergy agent developed by Teikoku Seiyaku. Rupafin is Japan’s first anti-histamine that has anti-PAF* action.

*Platelet Activating Factor. Closely involved in the pathology of allergies.
I originally joined the Company as an MR. As I confronted the various issues that MRs typically face, I began to think that I would like to work in a position that offers support from the perspective of MR development. That ambition was fulfilled, and in 2010 I was assigned to the Sales Force Training Office. I subsequently worked in MR development, including both operations and knowledge. In particular, my work in the formulation and adoption of solution maps* has been an extremely valuable experience.

In April 2018, I became the manager of this sales office, and MR development is still an important part of my responsibilities as manager. In regard to MR development, I believe that it is important to foster independent action. I am working to ensure that we share common objectives as a sales office, and at the same time I am also encouraging all employees to think for themselves about specific measures to achieve those objectives. In this way, I believe that each individual MR will focus on sustained success rather than being satisfied with short-term results.

However, promoting independence does not mean simply leaving things up to the individual. Follow-up is also important. For example, as a new initiative at this sales office we are strengthening the provision of information to medical institutions that account for only a small share of our sales but nonetheless have a high degree of potential. To that end, we are conducting strategy meetings in which participants share their insights and discuss effective measures. In this way, we are supporting the activities of individual MRs.

In regard to the independent action of MRs, I believe that the most important point is to give serious consideration to how our actions benefit patients. I also believe that acting for the benefit of patients is connected to the implementation of the solution maps that I mentioned above. Moving forward, I will continue to emphasize working for the benefit of patients, so that all of our MRs can have confidence that they are contributing to patients and society as they strive to carry out their duties each day.

* A systematic approach to processes that are models for the provision of information to health care professionals, based on analyses of the actions of Company MRs with superior results.
Overview and Sales Trends of Priority Products in Fiscal 2018

The sales forecasts in this section were announced on May 9, 2018.

### Revenue of Priority Products in Fiscal 2018

<table>
<thead>
<tr>
<th>Product</th>
<th>'14</th>
<th>'15</th>
<th>'16</th>
<th>'17</th>
<th>'18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remicade</td>
<td>70.6</td>
<td>69.4</td>
<td>66.8</td>
<td>64.6</td>
<td>55.5</td>
</tr>
<tr>
<td>Simponi</td>
<td>10.4</td>
<td>12.9</td>
<td>24.9</td>
<td>32.1</td>
<td>35.0</td>
</tr>
<tr>
<td>Tenelia</td>
<td>6.2</td>
<td>14.1</td>
<td>16.5</td>
<td>17.5</td>
<td>17.0</td>
</tr>
<tr>
<td>Talion</td>
<td>15.9</td>
<td>16.8</td>
<td>18.9</td>
<td>16.9</td>
<td>7.3</td>
</tr>
<tr>
<td>Lexapro</td>
<td>7.9</td>
<td>9.5</td>
<td>11.2</td>
<td>12.7</td>
<td>13.1</td>
</tr>
<tr>
<td>Canaglu</td>
<td>1.1</td>
<td>0.5</td>
<td>3.4</td>
<td>5.6</td>
<td>7.6</td>
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<tr>
<td>Imusera</td>
<td>3.2</td>
<td>4.1</td>
<td>4.9</td>
<td>4.7</td>
<td>4.9</td>
</tr>
<tr>
<td>Canalia (new product)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1.8</td>
<td>3.2</td>
</tr>
<tr>
<td>Rupafin (new product)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>0.4</td>
<td>6.8</td>
</tr>
<tr>
<td>Vaccines:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza vaccine</td>
<td>7.3</td>
<td>13.7</td>
<td>12.7</td>
<td>9.9</td>
<td>11.2</td>
</tr>
<tr>
<td>Tetrabik</td>
<td>7.5</td>
<td>9.5</td>
<td>9.9</td>
<td>8.7</td>
<td>9.1</td>
</tr>
<tr>
<td>Varicella vaccine</td>
<td>7.1</td>
<td>6.3</td>
<td>5.4</td>
<td>5.2</td>
<td>5.5</td>
</tr>
<tr>
<td>JE Bik V</td>
<td>3.5</td>
<td>3.6</td>
<td>3.9</td>
<td>5.2</td>
<td>4.3</td>
</tr>
<tr>
<td>Me Rubik</td>
<td>3.9</td>
<td>4.9</td>
<td>5.9</td>
<td>5.0</td>
<td>5.5</td>
</tr>
</tbody>
</table>

Note: From fiscal 2016, the Company has voluntarily applied IFRS instead of Japanese GAAP. Figures for fiscal 2015 are also presented in accordance with IFRS, but figures for fiscal 2014 are before the application.
Remicade
Infliximab

Indications
RA (including the prevention of structural joint damage), Behcet’s disease with refractory uveoretinitis, psoriasis vulgaris, psoriasis arthropathica, pustular psoriasis, erythrodermic psoriasis, ankylosing spondylitis, entero-Behcet’s disease, neuro-Behcet’s disease, vasculo-Behcet’s disease, Kawasaki disease, Crohn’s disease, ulcerative colitis

Launch May 2002
Origin Janssen Biotech (U.S.)
Development Mitsubishi Tanabe Pharma

Overview Remicade is the world’s first anti-TNF monoclonal antibody. It targets TNF, an inflammatory cytokine. Administered through IV infusion, it is very fast-acting and its efficacy is sustained for eight weeks with a single administration. In Japan, it was launched as a treatment agent for Crohn’s disease in 2002 and received an additional indication for RA in 2003. In 2009, approval was received for a change of dosage / administration for RA (increased dosage, shortened administration interval). Furthermore, additional indications for a wide range of inflammatory autoimmune diseases, such as psoriasis and ulcerative colitis, have contributed to growth in sales. In 2012, it became possible to shorten the IV infusion time from the 4th administration if there are no problems with safety. Also, in fiscal 2017 approval was received for a partial change in administration / dosage (shortened administration interval) for Crohn’s disease.

Sales Trend In fiscal 2017, revenue was down 3.2%, to ¥64.6 billion. NHI drug prices were revised in April 2018, and the third biosimilar is expected to be launched during fiscal 2018. The circumstances will remain difficult, including competing products. However, in the treatment of RA, we will work to enhance original value by facilitating contributions to the optimization of treatment through the use of blood concentration measurement kits. The forecast for revenue in fiscal 2018 is ¥55.5 billion, a decline of 14.1%.

Simponi
Golimumab

Indications
RA (including the prevention of structural joint damage), ulcerative colitis

Launch September 2011
Origin Janssen Biotech (U.S.)
Development Co-development with Janssen Pharmaceutical K.K.

Overview Simponi is a human TNFα monoclonal antibody that targets TNFα, an inflammatory cytokine. With simple administration—subcutaneous injection once every four weeks—it has superior efficacy that continues for an extended period of time. Its efficacy and safety are higher than other subcutaneous injections, and it is expected to contribute to raising the percentage of patients who continue treatment. In regard to indications, in addition to RA (including the prevention of structural joint damage), in 2017 Janssen Pharmaceutical K.K., with which we are conducting joint development, added an indication for ulcerative colitis.

Sales Trend In fiscal 2017, revenue rose 29.0%, to ¥32.1 billion. The convenience of a single administration for a four-week period has been highly evaluated, and Simponi is increasing its share in the RA market. In addition, in the ulcerative colitis market, it is used by a growing number of institutions as the third biologic. In April 2018, insurance coverage was extended to include self-administered injections for the treatment of RA, which provides a new treatment option for patients who face difficulties in commuting to medical facilities. In fiscal 2018, new competing products are expected to be launched, and the market environment will be challenging. However, we will leverage our collaborative alliance with Janssen Pharmaceutical K.K. and work to promote the further use of Simponi. The forecast for revenue in fiscal 2018 is ¥35.0 billion, an increase of 9.2%.
### Tenelia

**Teneligliptin**

**Indication**
Type 2 diabetes mellitus

**Launch**
September 2012

**Origin**
Mitsubishi Tanabe Pharma

**Development**
Mitsubishi Tanabe Pharma

**Domestic Revenue**
¥17.5 billion

**Overview**
Tenelia is the first dipeptidyl peptidase-4 (DPP-4) inhibitor originating in Japan that has ever been launched. Due to the strength and duration of its action, it can improve post-prandial blood glucose, after three meals, with once-a-day oral administration. Furthermore, because it is eliminated from the body via two routes—through the kidneys and the liver—it is not necessary to adjust the dosage for patients with impaired kidney function. In 2013, approval was received for an indication of additional combination for type 2 diabetes mellitus, making it possible to use Tenelia in combination with all oral diabetes mellitus treatment agents and insulin.

**Sales Trend**
In fiscal 2017, revenue rose 5.8%, to ¥17.5 billion. Competition in the DPP-4 inhibitors market is intense, but we have implemented joint promotional activities with Daiichi Sankyo and achieved solid increases in the number of administrations. From 2015, to increase efficiency we changed from a joint sales scheme to solo marketing by Daiichi Sankyo. However, we continue to implement joint promotions, and are emphasizing its ease-of-use and strong effectiveness, such as for senior citizens and patients with impaired kidney function. Accompanying the change in the sales scheme, the total of the amount of the Company’s sales to Daiichi Sankyo, and the amount of promotion fees received from Daiichi Sankyo is disclosed as the amount of revenue from Tenelia. The forecast for revenue in fiscal 2018 is ¥17.0 billion, a decrease of 2.8%.

### Talion

**Bepotastine**

**Indications**
Allergic rhinitis, urticaria, pruritus accompanying skin disease (eczema, dermatitis, prurigo, cutaneous pruritus)

**Launch**
October 2000

**Origin**
Ube Industries

**Development**
Co-development with Ube Industries

**Domestic Revenue**
¥16.9 billion

**Overview**
Talion has rapid onset of histamine H1 receptor antagonist effects and quickly displays a high degree of effectiveness for allergic rhinitis, urticaria, and pruritus accompanying dermatitis. It has a low frequency of sedation, which is a side effect of anti-histamines. An orally disintegrating tablet formulation, which makes it easier for patients to take the drug, has been sold since 2007, and a pediatric indication (ages 7 to 15) was approved in 2015.

**Sales Trend**
In fiscal 2017, sales declined 10.7%, to ¥16.9 billion. In March 2018, an authorized generic was launched. (An authorized generic is a product that is sold through a subsidiary, affiliate, etc., when that company receives patent usage rights from the pharmaceutical company that manufactures and sells the original product.) In addition, a generic drug was launched in June. However, during the reexamination period we will focus on pediatric applications (ages 7 to 15). The forecast for revenue in fiscal 2018 is ¥7.3 billion, a decrease of 56.6%.
Lexapro

**Escitalopram**

<table>
<thead>
<tr>
<th>Domestic Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>¥12.7 billion</td>
</tr>
</tbody>
</table>

**Overview**
Lexapro is a selective serotonin reuptake inhibitor (SSRI). It was launched in 2002 in Europe and the U.S., and is currently approved in approximately 100 countries and regions. Among SSRIs, it has the highest serotonin transporter selectivity. Its superior efficacy for depression and depressive symptoms and good tolerability have been confirmed. In addition, it has simple administration, and as a result it is expected to contribute to the improvement of medication adherence, which is especially important in patients with depression. We have been conducting joint sales activities with Mochida Pharmaceutical since 2011. In 2015, it received an additional indication for social anxiety disorder (SAD).

**Indications**
Depression, depressive symptoms, social anxiety disorder

<table>
<thead>
<tr>
<th>Launch</th>
<th>August 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Origin</td>
<td>H. Lundbeck (Denmark)</td>
</tr>
<tr>
<td>Development</td>
<td>Mochida Pharmaceutical</td>
</tr>
</tbody>
</table>

**Sales Trend**
In fiscal 2017, revenue rose 13.2%, to ¥12.7 billion. Recognition of Lexapro’s efficacy and tolerability has begun to achieve further market uptake, and Lexapro has secured the top share in the SSRI market. With an additional indication for SAD, we will work to promote its use by patients with anxious depression. In addition, for consideration of the pediatric dosage the reexamination period was extended by two years. The forecast for revenue in fiscal 2018 is ¥13.1 billion, an increase of 3.1%.

Canaglu

**Canagliflozin**

<table>
<thead>
<tr>
<th>Domestic Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>¥5.6 billion</td>
</tr>
</tbody>
</table>

**Overview**
Canaglu is an SGLT2 inhibitor that originated in Japan. It has been approved in more than 80 countries around the world, including the U.S., European countries, and Australia. It is based on the SGLT inhibitor T-1095, which was discovered by the Company and is the world’s first orally administered SGLT inhibitor. SGLT2 inhibitors promote urinary glucose excretion and blood glucose reduction. In this way, SGLT2 inhibitors have a new mechanism of action that was not previously available and does not work through insulin. In addition to a strong blood glucose lowering effect, SGLT2 inhibitors are expected to have a low hypoglycemia risk in monotherapy. SGLT2 inhibitors also have a weight reduction effect that is not seen with other oral diabetes treatment drugs. In overseas markets excluding Asia, licensee Janssen Pharmaceuticals, of the U.S., received approval in the U.S. in 2013, making this drug the first SGLT2 inhibitor approved in the U.S., and this drug is sold under the brand name Invokana.

**Indication**
Type 2 diabetes mellitus

<table>
<thead>
<tr>
<th>Launch</th>
<th>September 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Origin</td>
<td>Mitsubishi Tanabe Pharma</td>
</tr>
<tr>
<td>Development</td>
<td>Mitsubishi Tanabe Pharma</td>
</tr>
</tbody>
</table>

**Sales Trend**
In fiscal 2017, revenue was up 60.8%, to ¥5.6 billion. Moving forward, we will work to see that Canaglu rapidly catches up to SGLT2 inhibitors that were launched earlier by securing accounts at hospitals and by differentiating it from other drugs in the private practitioner and small hospital market. On a base of abundant evidence for Canaglu, which is the world’s most prescribed SGLT2 inhibitor, we will advance appropriate information provision activities and work to promote the appropriate use of SGLT2 inhibitors while fostering an understanding of the usefulness of this drug. The forecast for revenue in fiscal 2018 is ¥7.6 billion, an increase of 36.5%.

**Mitsubishi Tanabe Pharma Corporate Report 2018**
Overview

The Company sells vaccines developed and produced by The Research Foundation for Microbial Diseases of Osaka University (BIKEN Foundation). In May 2017, aiming for a stable supply of high-quality vaccines that are competitive in Japan and overseas, the BIKEN Foundation and the Company established a joint venture company, BIKEN Co., based on the BIKEN Foundation’s vaccine manufacturing business. On a base of the BIKEN Foundation’s vaccine manufacturing technologies, BIKEN Co., will leverage Mitsubishi Tanabe Pharma’s pharmaceutical production-related systems and management methods and accelerate the reinforcement of the production foundation. In this way, BIKEN Co., will aim to achieve a more stable supply of vaccines.

Sales Trend

In fiscal 2017, overall revenue from vaccines was down 10.0%, to ¥35.0 billion. The Company maintained the top share of the domestic vaccine market in fiscal 2017. For the seasonal influenza vaccine, which accounts for the largest share of the Company’s sales of vaccines, intradermal and cell-culture vaccines have been developed, but their influence on the market is not clear and it is not possible to make specific market forecasts. For the varicella vaccine, the number of children receiving periodic vaccination and the supply both stabilized. Accordingly, from fiscal 2017 we focus on promotions to prevent shingles in people 50 or older. However, the effect on the market has been small because this is a voluntary vaccination. The forecast for overall revenue of vaccines in fiscal 2018 is ¥36.5 billion, an increase of 4.2%.

Imusera

Overview

Imusera is a first-in-class drug that controls inflammation in the brain and spinal cord in MS. It inhibits the receptor function of the sphingosine-1-phosphate (S1P) receptor on the lymphocyte, and prevents auto-aggressive lymphocytes from invading the central nervous system. Unlike previous drug treatments for MS, which are limited to injections, it can be administered orally (once daily), thereby lowering the burden on patients. Imusera was discovered by Mitsubishi Tanabe Pharma and developed jointly by Mitsubishi Tanabe Pharma and Novartis Pharma K.K. in Japan. We are marketing this product under the name Imusera, while Novartis Pharma K.K. is marketing it under the name Gilenya. Overseas, Novartis, of Switzerland, which licensed the product, has obtained approval in more than 80 countries and regions, including countries in Europe and the U.S.

Sales Trend

In fiscal 2017, revenue was down 3.5%, to ¥4.7 billion. New competing product was launched in February 2017, but based on their combined results Imusera and Gilenya have maintained the No. 1 share in the market. Moving forward, we anticipate a shift from injections toward oral drugs, and patients will have a choice of two oral drugs in accordance with their condition. The forecast for revenue in fiscal 2018 is ¥4.9 billion, an increase of 5.4%.
New Products Launched in Fiscal 2017

Canalia
Teneligliptin/canagliflozin

**Overview**
Canalia is a type 2 diabetes mellitus treatment agent that combines Canaglu and Tenelia. It is the first combination drug launched in Japan that includes a DPP-4 inhibitor and an SGLT2 inhibitor. Canalia has two different mechanisms of action, with the DPP-4 inhibitor promoting the secretion of insulin in accordance with blood glucose level and the SGLT2 inhibitor promoting the excretion of glucose into urine. Accordingly, it is expected to offer good blood glucose control with a single tablet administered once per day. In addition, in clinical trials in Japan targeting patients for whom mono-therapy with Tenelia or Canaglu is not sufficiently effective, favorable results have been confirmed in regard to efficacy and safety.

**Sales Trend**
In fiscal 2017, revenue was ¥1.8 billion. Since its launch in September 2017, product recognition and intention to prescribe have been high, and sales have followed a favorable trend. In fiscal 2018, a competing product is expected to be launched, and domestic needs for combination tablets are increasing against a background of declines in the number of tablets taken and in the NHI drug price burden. Accordingly, we will work to foster further uptake in the market by providing information about the characteristics of Canalia. The total of the amount of the Company's sales to Daiichi Sankyo and the amount of promotion fees received from Daiichi Sankyo is disclosed as the amount of the Company's revenue. The forecast for revenue in fiscal 2018 is ¥3.2 billion, an increase of 79.6%.

Rupafin
Rupatadine fumarate

**Overview**
Rupafin is an oral allergy treatment agent that has a new mechanism of action. In addition to anti-PAF (platelet activating factor) action, it also has anti-histamine action. Launched in 2001 in Spain, it is currently approved in more than 80 countries and regions. Like histamine, PAF is a chemical transmitter that is closely involved in the pathology of allergic disorders. PAF induces vasodilation, vascular permeability enhancement, sensory nerve stimulation, and white blood cell activation. As a result, it brings about such symptoms as sneezing and runny nose. By simultaneously controlling PAF and histamine, Rupafin offers strong effectiveness and controls the symptoms of allergic disorders.

**Sales Trend**
Sales commenced in November 2017, and in fiscal 2017 revenue was ¥0.4 billion. The number of patients with hay fever and other allergic disorders is increasing each year. By simultaneously controlling both PAF and histamine, Rupafin offers dual action that is not available from existing anti-histamine products. Rupafin is a highly effective product, and on that basis we will work to increase its share by implementing sales activities to promote a switch from existing anti-histamine products. The forecast for revenue in fiscal 2018 is ¥6.8 billion, a substantial increase.
Basic Policy

“Accelerating U.S. Business Development” is one of the four strategic priorities in Medium-Term Management Plan 16–20, and the Company has set a numerical target of ¥80.0 billion in U.S. revenue in fiscal 2020. We have outlined three steps for the roadmap toward the achievement of that target as well as sustained growth in fiscal 2021 and subsequent years.

The first step was getting the U.S. business under way with the launch of Radicava. The second step will be a focus on expanding the U.S. business through the active use of strategic investment and other measures. The current medium-term management plan calls for the implementation of more than ¥200.0 billion in strategic investment. The third step will be the continued growth of the U.S. business through initiatives in new disease areas in addition to neurological disorders and vaccines. These initiatives will be implemented on the business foundation that the Company establishes with the first and second steps.

Smooth Launch for Radicava

We took the first step in August 2017 with the launch of Radicava. In the U.S. business, we use the term “the three Ps” to refer to our key stakeholders—Patients, Physicians, and Payers. We have been working with these stakeholders to foster an understanding of Radicava’s product value, and have been taking steps to enhance the treatment...
In August 2017, Mitsubishi Tanabe Pharma took the first step in the development of its U.S. business with the launch of Radicava, an ALS treatment agent. This section explains our business strategy for developing the U.S. business into the Company’s second operational pillar following Japan, as well as our initiatives with Medicago and NeuroDerm.

environment, such as measures to provide and expand information regarding medical institutions that prescribe Radicava.

As a result of these efforts, the number of patients who have taken Radicava surpassed 3,000 in August 2018. Radicava has gotten off to a strong start, and revenue in fiscal 2017 reached ¥12.3 billion. Moving forward, we will continue working to promote appropriate usage and to increase recognition of Radicava through the provision of information to health care professionals. In addition, we will focus on measures to enhance Radicava’s accessibility and take steps to improve the ALS treatment environment, including support for at-home care. In these ways, we will advance a range of measures for the three Ps.

Moreover, at the same time we will implement Companywide initiatives to maximize the product value of Radicava. We filed an application in Switzerland in December 2017, followed by applications in Canada in April 2018 and Europe in May 2018. In the future, we will consider extending these measures to ASEAN markets and other regions. Furthermore, we are also working to advance life-cycle management strategies, such as the development of dosage forms for new administration routes. We are forecasting Radicava revenue in the U.S. of ¥31.5 billion in fiscal 2018. Going forward, we will continue working to achieve growth for Radicava and to deliver this treatment agent to as many ALS patients as possible around the world.

Taking On the Challenge of Achieving Numerical Targets through Strategic Investment

Targeting the second step—expanding our U.S. business—we will work to follow up Radicava by enhancing our pipeline in the area of neurological disorders. To that end, in October 2017 we acquired NeuroDerm, of Israel, for approximately ¥124.0 billion (approximately US$1.1 billion), and made it a wholly owned subsidiary. NeuroDerm is a pharmaceutical company with excellent capabilities in the development of technologies that combine drugs and medical devices. It is advancing the development of new drugs, centered on ND0612, a treatment agent for Parkinson’s disease. In addition, in fiscal 2017 Medicago, of Canada, started phase 3 trials for MT-2271, a plant-based VLP vaccine. Plans call for an application to be filed in fiscal 2018, and this product is expected to be launched during the period of the current medium-term management plan.

We will continue to implement strategic investment, and will obtain products, drug candidates, etc., from external sources. In these ways, we will work to expand our U.S. business and achieve ¥80.0 billion in U.S. revenue in fiscal 2020.

Building a Foundation for Sustained Growth

First-step and second-step initiatives—such as maximizing sales of Radicava and rapidly developing and launching ND0612 and MT-2271—are issues that we will have to address in order to achieve the numerical targets in the medium-term management plan. On the other hand, to realize sustained expansion in our U.S. business, which is positioned as the third step, we need to further enhance our pipeline and steadily advance development of in-house products.

We believe that the most important issue in accelerating U.S. business development is the implementation of measures and the establishment of systems to foster sustained growth in fiscal 2021 and thereafter, while at the same time pursuing short-term results, including the achievement of our numerical targets. To that end, we will need to implement the principles of selection and concentration in our R&D investment, with an early-stage focus on products developed in-house. Currently, at Mitsubishi Tanabe Pharma Holdings America (MTHA), we are working to strengthen the market analysis function in order to appropriately address the needs of patients and health care professionals. We will work to maximize pipeline value, including accelerating the development of in-house products, by seamlessly linking the creation of products that meet market needs and the formulation of sales strategies. We will also strive to rapidly nurture products that have been launched and to maximize their sales.

Furthermore, in fiscal 2017 the administrative functions of Group companies in the U.S., including human resources, legal affairs, accounting and finance, IT, and general affairs, were transferred to MTHA. Going forward, we will also simultaneously advance measures to reinforce defensive functions in the U.S. business, such as further bolstering governance and compliance through changes in the organizational system.

Our role will be to make full use of the Company’s management resources and to achieve a balance between proactive initiatives (strategic investment and function reinforcement) and defensive initiatives (bolstering governance and compliance). We will take steps to ensure sustained growth in the U.S. business while also pursuing results in the short term. With the launch of Radicava, the U.S. business is expanding rapidly. I believe that society’s expectations of our business, as well as the duties and responsibilities that are our obligations to society, are expanding on a daily basis. To develop the U.S. business into Mitsubishi Tanabe Pharma’s second operational pillar following Japan, we will steadily complete the three steps.

For further information about the specific initiatives of Medicago and NeuroDerm, please refer to Page 38–39.
Medicago was established in Canada in 1997—the result of a collaboration between Laval University and the Ministry of Agriculture. The Quebec-based company was publicly funded until late 2013, when Japan’s Mitsubishi Tanabe Pharma Group and Switzerland’s Philip Morris International (PMI) made a joint venture agreement to support its future development.

Medicago is a biopharmaceutical company specializing in the research and development of new vaccines and other therapeutic proteins. To produce vaccines, Medicago has developed an innovative technology that uses plant as mini factories to produce VLPs. VLPs have the same external structure as viruses; when administered as a vaccine, they stimulate the human immune system and are expected to provide strong protection against the viruses they imitate. However, because VLPs do not include any genetic material, there are no risks of replication and infectious disease. Medicago’s proprietary technology uses transient gene expressions in non-genetically modified plants. The plant species used is Nicotiana benthamiana.

Typically, in the case of producing the influenza pandemic, egg-based vaccines take around five to six months to manufacture a vaccine with this technique. In contrast, Medicago’s plant-based VLP methods require just five to six weeks. With such a short production timeline, Medicago could make a real difference if another influenza pandemic, such as the 2009 H1N1 pandemic, were to occur. The rapid availability of a vaccine during such a devastating event could help reduce the number of people infected, reduce overall morbidity and mortality, and minimize the socio-economic disruptions of a pandemic.

In addition, it is well known that the chicken-egg manufacturing process can cause the virus to mutate suddenly, meaning that the strain in the vaccine no longer exactly matches the target strain. When that happens, the effectiveness of the seasonal egg-based vaccine is reduced and the risk of infection increases. The social and economic losses can be substantial. This problem does not exist in plant-based vaccines; the VLP produced by Medicago’s manufacturing process always matches the circulating strain.

Under its current medium-term management plan, Mitsubishi Tanabe Pharma has positioned the vaccine business as a priority disease area, both in Japan and overseas. Moving forward, we will take steps to advance new vaccine development through Medicago’s VLP vaccine technology, with a focus on the U.S.

**MESSAGE**

To achieve the launch of plant-based VLP vaccines, we want to make sure that all employees have a clear view and understanding of Medicago’s short- and long-term goals.

In the short term, we need to begin preparing for the early New Drug Application for MT-2271, which will be Medicago’s first product. This involves maintaining focus and motivation across all departments. We will also encourage a culture of entrepreneurship and efficient decision-making at all management levels to maximize effort and minimize distractions.

Medicago’s technology platform represents a truly disruptive approach not only to vaccine development and production, but also to many biologics. The VLP platform is incredibly versatile and efficient. Our goal at Medicago is to become the global leader in innovative product development using plant-based technology. We initially intend to demonstrate our capability through our VLP vaccine development program. However, our platform also has the potential to develop new therapies that combine vaccines and antibodies, both of which can be produced with the same VLP technology.

Bruce D. Clark
President & CEO
Medicago
NeuroDerm, a pharmaceutical company that was established in Israel in 2003, has joined the Mitsubishi Tanabe Pharma Group. NeuroDerm has proprietary production technology for liquefying insoluble compounds, and through combinations of pharmaceuticals and devices, the company is developing treatment agents with high clinical value that offer increased effectiveness in addressing unmet medical needs and reduced side effects.

ND0612, for example, is under development in the U.S. and Europe with an expected indication of Parkinson’s. Parkinson’s is a progressive neurodegenerative disorder, with the onset of symptoms typically occurring when patients are in their 40s, 50s, or thereafter. The number of patients is said to be approximately 1 million in the U.S., 1.4 million in Europe, and 0.1 million in Japan. Furthermore, accompanying the aging of society, the number of patients is increasing.

Parkinson’s disease occurs due to a deficiency of dopamine, a neurotransmitter that works in the brain. Accordingly, drug therapy is widely used to compensate for the dopamine deficiency through the administration of levodopa as an oral preparation. Patients are generally prescribed a combination drug that includes carbidopa, which inhibits the breakdown of levodopa. However, oral levodopa has a short half-life and, as Parkinson’s disease progresses, it becomes difficult to stabilize the blood levodopa concentration, and as a result the number of administrations per day has to be increased while the clinical effect of the treatment deteriorates. In addition, as the disease progresses to moderate and severe stages, treatment with drug therapy becomes difficult, and treatment methods that involve surgical intervention and place a larger physical burden on patients must be selected.

Through proprietary formulation technology, NeuroDerm achieved a world first with the successful liquefaction of levodopa and carbidopa, which are oral treatment agents. ND0612 is a treatment agent that can be administered through subcutaneous injection in a sustained manner for 24 hours through the combination of liquified levodopa and carbidopa with a mobile pump. There are high expectations for ND0612 as a new drug that addresses unmet medical needs for Parkinson’s by making it possible to stabilize the blood concentration of levodopa in patients with moderate to severe symptoms.

MESSAGE

The acquisition of NeuroDerm by Mitsubishi Tanabe Pharma marks an important milestone in NeuroDerm’s long road to develop a new pharmaceutical product, a road that involves hard work, dedication, ingenuity, creativity, and above all, integrity and commitment to do good in this world. But we are not there yet, we have a lot more to do. And now we will do it as part of a large, global group that shares our values.

Mitsubishi Tanabe Pharma has shown incredible vision and courage when deciding to add NeuroDerm to the Group. We will do our best to prove that we can make a big change in the lives of Parkinson’s patients; that we can generate new combination “Designed Pharmaceuticals” drug-device combination products, more rapid and less risky to develop, that have great impact on the lives of patients; and that we can change the world for the better. Wishing all of us the best of success in our mutual journey!
Establishment of the Production Technology & Supply Chain Management Division

In April 2018, the Company consolidated the CMC Division (CMC: see the “Explanation of Terms” section) and the *monozukuri* functions of the Production Division to establish the new Production Technology & Supply Chain Management Division. The new division’s role will be to advance the entire range of *monozukuri* activities more smoothly and flexibly, from the investigational drug products used in the initial stages of clinical trials to post-marketing product manufacturing and supply.

There are two major reasons for the establishment of the Production Technology & Supply Chain Management Division. The first is steady progress for development projects. We will contribute to maximizing pipeline value by shortening the development period and implementing other initiatives. The second is the establishment of production technology and supply chain management that is able to adjust to changes in the business environment. To that end, we will advance a range of measures, such as global supply chain management and CMC organization maintenance, optimization of manufacturing bases, reduction in cost of goods sold, and reinforcement of *monozukuri*.

Steady Progress for Development Projects

The domestic market environment is challenging, and in this setting we will need to launch products as rapidly as possible in the U.S., Europe, and other overseas markets. This is an important issue for the entire Company. In addition, R&D targets have expanded to include a wider range of modalities1, from small-molecule drugs to biologics, cell therapy drugs, nucleic acid drugs, etc. In comparison with small-molecule pharmaceuticals, it is more difficult to develop these types of products to the point where they are suitable for commercial production, and the ability to quickly set a target for commercial production is significantly connected to development speed. Accordingly, the role of *monozukuri* is increasingly important in drug development. Previously, the CMC Division was positioned upstream (R&D) in the drug development value chain and the Production Division was positioned downstream (production and supply). However, in consideration of these business environment changes, we decided that we would need to implement structural reforms to our *monozukuri* organization, with a view extending from upstream to downstream. Accordingly, we established the Production Technology & Supply Chain Management Division. Furthermore, the CMC Division had strengths in active pharmaceutical ingredients and pharmaceutical technologies, while the Production Division had strengths in commercial production technologies. The Production Technology & Supply Chain Management Division...
This section explains our initiatives regarding the entire range of *monozukuri* (manufacturing with production technology and supply chain management) activities, from the investigational drug products used in the initial stages of clinical trials to post-marketing product manufacturing and supply.

Supply Chain Management and CMC Organization Maintenance that Is Able to Adjust to Changes in the Business Environment

In August 2017, we launched Radicava in the U.S. We are also advancing initiatives for this product in Europe and other markets. In addition, new drug development is shifting to an overseas focus, centered on the U.S. In this setting, we believe that we will need to devote resources to the maintenance of a global supply chain management and CMC organization. However, it will be difficult for us to do everything in-house, and accordingly we will strengthen collaboration with external subcontractors.

With modalities expanding, it will be increasingly important to select external subcontractors that are suitable for such factors as product characteristics. We are continually working to gather information, and when necessary we visit local regions to select the external subcontractor. In addition, production processes are becoming more complex, and it is not a simple matter to transfer production technologies to external subcontractors. Previously, we addressed this issue through collaboration between the CMC Division and the Production Division. However, going forward we will aim to realize smoother technology transfers by consolidating our response through the Production Technology & Supply Chain Management Division.

In addition, reduction in the cost of goods sold is also an urgent issue. To reduce fixed costs, such as facilities and labor costs, in 2007 we optimized manufacturing bases from the system that we had utilized since the merger. Mitsubishi Tanabe Pharma Factory, a domestic production subsidiary, had five manufacturing bases, which have been consolidated into two bases, the Onoda Plant and the Yoshitomi Plant. On the other hand, to reduce variable costs, such as for raw materials, we are taking steps to strengthen our production technologies, such as developing technology for low-cost production of intermediates for active pharmaceutical ingredients. In addition, we are working to reduce procurement and distribution costs. Furthermore, we have consolidated *monozukuri* functions into the Production Technology & Supply Chain Management Division. As a result, in addition to these types of post-marketing initiatives, I believe that we will be able to conduct highly cost competitive product development from the initial stages of clinical trials.

Outlook for Fiscal 2018 and Thereafter

In fiscal 2018, we will advance initiatives targeting the rapid start-up of a *monozukuri* system suitable for the launch of Radicava in countries and regions outside the U.S. and for the launch drug candidates in late-stage clinical trials, such as ND0612 and MT-2271. Moreover, for MT-8554, MT-7117, MT-2990, and other drug candidates that are in early stage clinical trials, we will promote steady yet rapid development, and will take on the challenge of developing future technologies, such as continuous manufacturing technologies.

As a unit created through the consolidation of two divisions, the Production Technology & Supply Chain Management Division must leverage its unique capabilities to take on a variety of challenges while continuing to move forward with the initiatives that were being implemented by its two predecessors, such as the Production Division’s measures targeting stable supply and quality.

I believe that the key to making the whole greater than the sum of the parts is to develop supply chain managers who are globally active and well versed in technology. In other words, it is the nurturing of human resources who have multifaceted capabilities that cover all *monozukuri* activities. To that end, we will need to promote communication among employees that clears away walls between divisions. Moreover, by ensuring that they gain experience in various departments, we will develop a large number of employees with careers extending across a wide range of areas in *monozukuri*.

Human resources development is not something that is completed in a short period of time. We need to take the time that is required and work persistently. I believe that this is essential in order for the Production Technology & Supply Chain Management Division to demonstrate its true value. I will lead the promotion of initiatives to move beyond unit boundaries and take the next step in *monozukuri*.

As a dedicated supply chain unit, we will strive to give concrete shape to a variety of measures addressing the global market.

For further information about initiatives to support value creation in the supply chain, please use the following URL.

### CSR Website

<table>
<thead>
<tr>
<th>Consumer Issues -- Manufacturing and Supply Chain</th>
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1. In drug development, treatment methods are classified by molecule, such as small molecule compounds; protein drugs, including peptide (middle molecule) drugs and therapeutic antibodies; nucleic acid drugs; cell therapy drugs; and regenerative medicine.

2. Technology under which raw materials and reactants are continuously introduced, reactions occur continuously, and products are manufactured successively.
Pharmaceutical Market Trends

Looking at growth rate estimates for pharmaceutical markets around the world, the markets in the U.S., Europe, China, and ASEAN are expected to record annual growth in the range of 3% to 8% over the period from 2017 to 2022. In other words, continued growth is anticipated in global markets.

On the other hand, the level of growth in our home market of Japan is approaching zero. One major reason is that the Japanese government is taking steps to control the increases in social security expenses resulting from expansion in the population of senior citizens. To that end, the government is rapidly reducing NHI drug prices, which are the official prices of ethical drugs, and promoting the use of generic drugs, etc. We do not expect this trend to change in the short term.

In general, NHI drug prices are revised once every two years, and the effect of these revisions differs in accordance with each company’s product portfolio. An NHI drug price revision was implemented in April 2018, and we estimate the effect on our fiscal 2018 revenue will be approximately ¥21.0 billion. In particular, the company will be significantly affected by the new G1/G2 rules. These rules are for long-listed drugs for which 10 years have passed since the launch of generic drugs. G1 products are defined as long-listed drugs for which the generic drug substitution rate is 80% or more, while G2 products are long-listed drugs for which the generic drug substitution rate* is less than 80%. Drug prices are to be lowered in stages, with G1 drug prices reduced to the level of the generic drug prices after 6 years and G2 drug prices reduced to approximately 1.5 times the generic drug prices after 10 years.

In addition, the government is considering the implementation of an NHI drug price revision accompanying an increase in the consumption tax rate in 2019. We believe that we need to consider our future business operations based on the assumption that the government will carry out increasingly severe NHI drug price revisions on an annual basis.

* Substitution rate = Number of generic drugs / (Number of original drugs for which there are generic competitors + Number of generic drugs)

Message from the Financial and Accounting Officer

Eizo Tabaru
Board Director
Managing Executive Officer
In charge of Finance & Accounting Department

Market Data

Worldwide Pharmaceutical Market
(including OTC products)
Bilions of U.S. dollars
1,200
900
600
300
0
CY '13 '14 '15 '16 '17
Japan North America Europe Others
Note: OTC drugs are included.
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Source: IQVIA (World Review Analyst 2018)
January 2013–December 2017,
Reprinted with permission

Domestic Ethical Drugs Market
(including OTC products)
Trillions of yen
12
9
6
3
0
FY '13 '14 '15 '16 '17
Amount of sales
Growth rate
Note: OTC drugs are included.
Copyright © 2018 IQVIA.
Source: IQVIA (Pharmaceutical Market)
April 2013–March 2018,
Reprinted with permission

Market Share of Generic Drugs
(Volume basis)
% 100
75
50
25
0
FY '09 '11 '13 '15 '17 '19
Fiscal 2020 target
(Ministry of Health, Labour and Welfare)
35.8%
Source: Ministry of Health, Labour and Welfare
Advancing Operational Productivity Reforms

“Reforming operational productivity” is one of the four strategic priorities in Medium-Term Management Plan 16–20. For fiscal 2020, the final year of the plan, we have established a numerical objective calling for reducing cost of sales by ¥8.0 billion and SG&A expenses by ¥12.0 billion, for a total of ¥20.0 billion in cost reductions in comparison with fiscal 2015.

In working to reform our operational productivity, we have focused on securing the resources for SG&A expenses and R&D expenses, which are increasing due to the acceleration of U.S. business development and the increase in late-stage drug candidates. However, as described above, the domestic market environment is becoming increasingly challenging at a pace exceeding expectations. Furthermore, our business environment is worsening to a greater extent than we envisioned when we formulated the current medium-term management plan. For example, Invokana royalty revenues are slowing down. Accordingly, we face an urgent issue, and need to do more than simply achieve the initial objectives.

In this setting, in fiscal 2017 we were able to achieve cost reductions of ¥14.0 billion, versus our target of ¥10.0 billion. In addition, for fiscal 2018 we have set an objective of ¥19.0 billion, and are on track to accelerate the achievement of that numerical objective. This is the result of the success of the measures that we have implemented. However, we will not be satisfied with these results. Rather, we will step up our efforts.

Reforming Employee Awareness

To overcome this challenging business environment and record growth in fiscal 2021 and thereafter, I believe that we need to foster a change in the ideas and awareness of each employee in regard to the manner in which we move our work forward. Previously, work was generally handled at the department level and then passed on to the next department. With that style of working, however, it will be difficult to survive in business environments where the speed of change has increased, including not only Japan but also the U.S. and Europe. To survive we must evolve. In this type of environment, we need to shift to a system under which all employees and organizational units advance their work in a way that is suitable for the business environment. We have to transition to a system that enables us to address increasing speed and intensifying competition.

There are always competitors in the market. Unless we advance our work at the same speed as our competitors, or even faster, we will not be able to compete successfully. We must continually ask ourselves to what extent we will complete our work and when we will finish it. I would like to see the Company achieve true reforms in operational productivity by leveraging the experience of employees and organizations in order to rapidly achieve objectives and resolve issues.

Moreover, when our attitudes change, our actions and statements will change. I also believe that it will be extremely important to foster a change in attitudes so that the objectives and issues of individual employees are approached from a Companywide viewpoint. We need to visualize issues from a Companywide perspective and strive to foster collaboration inside and outside the Group. In this way, we can implement measures that fully leverage the Company’s potential and always act with consideration for speed. We need to “transcend limits” and “fully achieve our goals to the end” I believe that these types of changes among individual employees will lead to changes in Mitsubishi Tanabe Pharma and will become the driving force that enables the Company to overcome the current challenging business environment and record sustained growth in the years ahead.

Reinvestment in growth strategies
Fundamental Approach to Human Resources

Mitsubishi Tanabe Pharma is working to further enhance its competitiveness and achieve sustained growth by giving individual employees the opportunity to demonstrate their full potential. To that end, we focus on our people as a management resource, and we operate the Comprehensive Management System for Human Resources. Furthermore, we are aiming to develop human resources who act in accordance with the guidelines of pride and sense of mission, challenge and innovation, trust and collaboration, and harmonious coexistence with society. In addition, under Medium-Term Management Plan 16–20 we are aiming to implement reforms to become a “pharmaceutical company that works with a sense of speed and is the first to deliver original value,” and on that basis we are working to “realize a corporate culture with a sense of speed and a profitable business structure.”

We are implementing a range of human resources development initiatives that address the ongoing globalization of our business. To that end, we are implementing not only on-the-job training but also various off-the-job measures to help employees learn about foreign cultures and develop business English skills. These measures include a variety of group training and language study programs. In fiscal 2017, we began to recruit volunteers for overseas training and to assign them to work at overseas bases.

Enhancing Personnel Training

To strengthen our corporate vitality and competitiveness, we must work to enhance the capabilities of our human resources, who are the source of that vitality and competitiveness. Aiming to develop people with key attributes, we support the development and demonstration of the capabilities of employees through the smooth coordination of four frameworks: employing diverse human resources, on-the-job and off-the-job training through management by objectives (MBO), transfers and rotations, and fair evaluations. To that end, we are enhancing individual capabilities through daily on-the-job and in-house training programs and through the assignment of the right person to the right place. The Company is also working to provide support for autonomous employee career management and individual skill development and to develop next-generation leaders and global human resources who will be future managers. In fiscal 2017, we started career consultations with the objective of enhancing career management support, and revised our training systems and self-education support programs in order to further expand our viewpoints and establish independent study habits. We entered the second year of MT-VIVID, a management rapid development program for the development of the next-generation of leaders, and will continue working to strategically develop managers. In addition, to develop global human resources, which is an increasingly urgent task, we commenced OJTO, a training program that particularly emphasizes on-the-job training initiatives overseas.

Actively Utilizing Diverse Human Resources

The Group has positioned its approach to diversity and inclusion as one of its management strategies. With the objective of leveraging diverse human resources and maximizing results, the Company is conducting human resources development to draw on the skills of diverse employees, establishing systems and frameworks that make it easy for diverse employees to do their jobs, and providing opportunities for a diverse range of people. Managers will implement diversity management to leverage diverse employees and maximize results, which will lead to the generation of synergies by each employee.

In regard to diversity, we take into account both visible diversity (gender, gender identity (including LGBT), age, career background, nationality, disability status, time restrictions due to childcare, nursing care, etc.) and non-visible diversity (knowledge, skills, experience, values, ways of thinking, etc.). Moving forward, we will enjoy these differences and strive to realize a corporate culture that can draw on differences as strengths.

In fiscal 2017, we conducted training for all managers on the implementation of diversity management. In addition, we took steps to enhance understanding of LGBT issues through lectures by LGBT people, and distributed ally stickers, which show understanding of and support for LGBT people. Furthermore, we offered nursing care seminars to deepen understanding of nursing care for those with an interest in this issue.

In regard to the enhancement of career opportunities for women, we continued to implement www28 training (www: abbreviation for Win–Win–Woman), which considers the careers of women who have not yet experienced such life events as marriage and childbirth. In addition, we provided free e-learning and online English conversation classes for employees on childcare leave in order to enable them to quickly enjoy active careers after they return to work. We also introduced external study sessions for employees on childcare leave, and started childcare support through babysitters as a measure to support both work and childcare. Moreover, we established consultation hotlines for childcare, nursing care, and LGBT issues.

The following table illustrates the percentage of female employees with second qualifications or higher in Management Specialist Positions:

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage of Female Employees with Second Qualifications or Higher</th>
</tr>
</thead>
<tbody>
<tr>
<td>'16</td>
<td>7.8%</td>
</tr>
<tr>
<td>'17</td>
<td>15.1%</td>
</tr>
<tr>
<td>'18</td>
<td></td>
</tr>
</tbody>
</table>

* Employees who serve in specialist and leadership roles, considered equivalent to subsection managers.
Initiatives to Raise Human Rights Awareness

The Mitsubishi Chemical Holdings (MCHC) Group signed the United Nations Global Compact (UNGC) in May 2006. As a member of the MCHC Group, the Mitsubishi Tanabe Pharma Group also respects the 10 principles of the UNGC, which address human rights, labor, the environment, and anticorruption, and upholds these principles in its business activities in line with its Corporate Behavior Charter. The Company’s Human Rights Awareness Promotion Committee, chaired by the president, plays a key role in advancing human rights education as one facet of the promotion of diversity. These measures include internal training for officers and employees. In addition, we are implementing Companywide human rights education initiatives, including collaboration with outside experts and participation in outside lectures.

Securing Occupational Health and Safety

Aiming to promote environmentally friendly activities and to realize workplaces where employees can work in a healthy, enthusiastic, safety, and comfortable manner, the Group is strengthening its initiatives in the areas of Environment, Health, and Safety (EHS).

Securing the safety of employees in business activities is our highest priority, and to that end we are implementing a range of initiatives. In particular, in regard to the prevention of disasters, we are maintaining and strengthening our environmental management capabilities. In addition, it is important to enhance the risk sensitivity of all employees in regard to safety in their work, and accordingly we are implementing a wide range of safety training. To eliminate workplace disasters, we will continue to implement highly effective training and activities to reduce risks related to facilities and operations. We will work to realize KAITEKI, which is being advanced by the entire Mitsubishi Chemical Holdings Group.

Employee Health Management

The Group considers health management to be an important issue for corporate management. In April 2016, to effectively and appropriately advance activities related to employee health, we formulated the MTPC Group Health Policy in accordance with our Philosophy, Vision, and Corporate Behavior Charter. We are striving to promote awareness of work–life balance, improve mental and physical health, and implement varied working styles.

The Group will further strengthen activities related to the promotion of employee health, including its approach to working-style reforms. From fiscal 2017, we have highlighted the issues of promoting working-style reforms, strengthening our mental health measures, bolstering measures to prevent lifestyle-related diseases, and cultivating health awareness among employees, and are already implementing initiatives to address these areas.

Implementation of Employee Survey

Since fiscal 2011, the Mitsubishi Tanabe Pharma Group has implemented employee surveys to provide a comprehensive understanding of employee attitudes toward their jobs and of the Company’s workplace environments in order to improve management initiatives. In fiscal 2017, many items recorded year-on-year gains, and in particular improvement was recorded in the item regarding how the Company values its employees. The overall indicator for management philosophy, management policies, and corporate culture reached a record-high level. On the other hand, a number of issues were identified. In consideration of these issues, we will strive to establish a work environment that facilitates dynamic managers and to implement career formation measures for professionals. In addition, we will take steps to establish workplaces in which diverse employees are able to work in a healthy, energetic, and active manner.

For further information about KAITEKI, please see the MCHC website.

For further information about initiatives to activate human resources, please use the following URL.

CSR Website

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<th>Labor Practices → Human Resources Development</th>
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Activating Human Resources

To increase labor productivity, Japanese companies are implementing working-style reforms, which are the focus of increasing attention. In this environment, there is growing activity in the area of promoting active careers for human resources through “employee health management.” In this section, the Company’s initiatives in this area are introduced by Kazumi Kuroda and Michiko Shigematsu from the Human Resources Department’s Health Promotion Group, which is in charge of health management measures for Mitsubishi Tanabe Pharma.

Advancing Health Management Measures

To increase labor productivity, Japanese companies are implementing working-style reforms, which are the focus of increasing attention. In this environment, there is growing activity in the area of promoting active careers for human resources through “employee health management.” In this section, the Company’s initiatives in this area are introduced by Kazumi Kuroda and Michiko Shigematsu from the Human Resources Department’s Health Promotion Group, which is in charge of health management measures for Mitsubishi Tanabe Pharma.

--- Please describe the specific initiatives of the Health Promotion Group.

Kuroda The operating environment for domestic pharmaceutical companies is increasingly challenging. In this setting, a significant role is played by human resources support initiatives, such as promoting active careers for diverse human resources and implementing working-style reforms. Health is indispensable for the achievement of maximum performance with limited human resources. Taking steps to ensure that employees are able to work in a healthy and energetic manner has a number of benefits. It increases their individual quality of life by enhancing their work lives, and it also bolsters the Company’s overall productivity and competitiveness. For the Company to achieve sustained growth, our role in implementing health management measures will be increasingly important.

The Human Resources Department’s Health Promotion Group was established in fiscal 2017 as a unit specialized in health management, centered on health care professionals. Over the short period since its establishment, the group has already rolled out a number of new measures. For example, we have introduced the i2 Healthcare (i2 HC) program and a three-year smoking cessation program. We also started a blood pressure management program by risk level. In addition, we introduced an external Employee Assistance Program* (EAP) to strengthen our mental health measures, and prepared a health white paper with the objectives of verifying the effectiveness of measures and understanding health issues.

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Shigematsu I will explain in more detail about i2 HC, which is an original platform developed by the MCHC Group with the objective of supporting employee and workplace health. When employees access a dedicated website, they can confirm a wide range of information on their personal page. In addition to employee health examination data and working-style data, this also includes data obtained from wristwatch-style wearable devices, such as numbers of steps, activity levels, and sleep data. In addition, with the information accumulated on this platform, we can understand health management issues that were previously difficult to monitor, facilitating a health management PDCA cycle, such as for the formulation of measures and the confirmation of results.

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Kuroda Within the MCHC Group, the Company took the lead in implementing i2 HC initiatives, which have gotten off to a good start. The Company lends wearable devices to employees after
obtaining their consent in regard to the provision of the acquired data to i2 HC. As of the end of 2017, 75% of employees had already given their consent. The major reason is that managers have actively taken the lead and given their consent. Also, as one of the events to commemorate the 10th anniversary of the Company, we worked together with the health insurance association to hold a charity walk using wearable devices. There were about 1,000 participants. Wearable devices were used to measure the number of steps taken by the employees, and the Company and the health insurance association jointly donated funds to ALS patient organizations, etc., with the amount of the donations based on the number of steps. I think that this was a successful example of initiatives to motivate employees to use i2 HC.

— The Company was selected for two consecutive years under the Health & Productivity Management Outstanding Organizations (White 500) program, which is promoted by the Ministry of Economy, Trade and Industry. In what areas was the Company highly evaluated?

Shigematsu This system recognizes companies, medical corporations, and others that have done a particularly good job at health management. In fiscal 2018, 541 companies, including Mitsubishi Tanabe Pharma, were recognized in the large enterprise category (White 500). A number of evaluation items have been established in accordance with a framework that includes management philosophy (awareness of leaders), organizational structure, systems / policy implementation, evaluation / improvement, and observance of laws and regulations / risk management. In evaluation / improvement, the Company received the highest evaluation in the industry for the item regarding understanding indicators for work hours / leave, etc.

Kuroda This recognition system looks at initiatives to build a platform for health management, and short-term initiatives alone are not highly evaluated. In 2013, Mitsubishi Tanabe Pharma commenced full-scale efforts to build a health management administration system, with a focus on the alignment of labor management and health management. In addition, in the same year we introduced a health management system with integrated control extending from health management to labor management. In 2016, with the objective of advancing activities related to employee health in an effective and appropriate manner, we formulated the MTPC Group Health Policy and the Health Management Rules, which give concrete shape to the policy. In these ways, we steadily advanced the establishment of a platform for the implementation of health management.

Shigematsu In addition, as feedback following this recognition, we received a comment that there was still room for improvement in regard to the prevention of lifestyle diseases, etc. In particular, in regard to the high smoking rate, we recognize smoking as a challenge. In fiscal 2017, we set specific numerical targets and launched a three-year smoking cessation program, and are advancing a variety of initiatives to achieve those targets. For example, in the first year we made every Friday a no-smoking day, with the smoking rooms in our offices closed all day. Next, in the second year smoking was prohibited during working hours, and the smoking rooms were closed outside of break time. In these ways, we are advancing in stages. In the final year, fiscal 2019, we will aim to completely prohibit smoking in buildings.

In implementing this program, at the end of the first year we asked employees to fill out a questionnaire. As a result, we understood that, overall, 86% of employees approved of the program, including smokers. In addition, it is clear that more than 60% of smokers want to quit at some point. I believe that the extent to which we can encourage these employees to quit smoking will serve as a demonstration of our abilities.

— Finally, what would the Health Promotion Group like to see people focusing on going forward?

Shigematsu The Health Promotion Group cannot implement all of the health management measures by itself. Moving forward, we will actively step up cooperative initiatives both inside and outside the Company. This collaboration will include not only related departments inside the Company but also the health insurance association and subcontractors, as well as joint research with external research institutions. Moreover, the Company has not appointed a chief industrial physician, and the current system handles health management for more than 5,000 employees with nine nurses, including the two of us. In this setting, in order to advance health management measures for employees who are temporarily reassigned and those who are posted overseas, as well as for the families who support the employees, we will need to take on the challenge of new initiatives that extend beyond current frameworks. To that end, we will implement various initiatives, such as establishing systems that utilize ICT to provide health support even in distant locations. The entire nine-person nursing staff will work together to contribute ideas and strive to realize them.

Kuroda Fiscal 2018 will be the second year since the establishment of the Health Promotion Group, and it will be a year for seeing the results of initiatives implemented to date. However, health management is something that will always continue, and accordingly not all initiatives will generate results in the short term. To help employees to enjoy healthy, more fulfilling lifestyles after they retire, I believe that the mission of the Health Promotion Group is to encourage them to deepen their understanding of health and to develop healthy habits. To that end, we will work to leverage a health management PDCA cycle as we pursue results one by one. In this way, we will strive to further enhance a range of health management measures as we move forward.