Business and Financial Strategy

Message from the President

Masayuki Mitsuka
President & Representative Director

Continuing our transformation to realize long-term business growth and contribute to extending healthy life expectancy

President's Message Topics

1. Long-term vision for our management direction
2. Strengths, risks, and opportunities
3. Addressing ESG challenges
4. Short-term business conditions and outlook

Message from the President

1 Long-term vision for our management direction

Question:

What value does the Company provide to society?

Answer:

Mitsubishi Tanabe Pharma benefits society by providing treatments and preventive medicines that contribute to extending healthy life expectancy.

The rapidly aging demographics of Japan and other developed nations is leading to a crisis point for the sustainability of social security systems. I believe that this makes it incumbent for pharmaceutical companies like ours to step up and contribute to society by creating pharmaceutical products and medical services that provide higher medical value while lowering medical costs.

The Mitsubishi Tanabe Pharma Group has always considered it to be important not just for people to live long lives, but to live long and healthy lives of comfort and joy. We believe pharmaceutical companies contribute to extending healthy life expectancy in three ways. The first is to help raise the quality of life by helping treat illnesses so patients can lead productive lives. Another is to contribute to the productivity of society by increasing the number of people working with their full energy. And the final way is to stop illness before it strikes or, in a word, provide "prevention." I believe that the products and services we offer contribute in all three of these ways and truly help people live long and healthy lives.

Remicade is an example of one of our products that helps raise the quality of life of patients and lifts the productivity of society. Remicade is the world's first monoclonal antibody preparation against TNF-alpha, while it has also exhibited positive results for various indications. Rheumatoid arthritis is becoming increasingly common as populations age, and in Japan some 700,000–800,000 people are suffering from the inflammatory disorder. The symptoms include intense joint pain and ultimately damaged joints to the degree that regular daily activities become difficult and painful. Although there is currently no cure for rheumatoid arthritis, Remicade is able to provide relief for many patients. A doctor once told me about its effects: "Remicade enabled an elderly farmer to be able to take care of her grandchild so her son and his wife could work the fields. It helped their whole family situation." So medicine we developed not only relieved one person's pain, it was also a catalyst for others to become more active and participate in the labor force. On a larger scale, I could see that medicine can have a big impact on local communities and could even bring smiles to people's faces.

Another area where we are particularly active is developing preventive medicines, particularly vaccines. The MTPC is one of just a handful of Japanese entities that is working in all aspects from R&D through to marketing to develop vaccines with the Research Foundation for Microbial Diseases of Osaka University. We are also developing drugs for other forms of preventive treatments. Recently, clinical trials overseas found that the canagliflozin treatment (marketed as Canaglu in Japan and Invokana in the U.S.) for type 2 diabetes helps inhibit the lifestyle disease from progressing to diabetic nephropathy (diabetic kidney disease). Canagliflozin treatment therefore shows promise for blocking diabetes from progressing into nephropathy and inhibiting the development of further complications.

Living a healthy life requires more than taking care of the body. It also means taking care of the mental aspects, such as maintaining positive relations with family members and the local community. A person who is living a healthy life is active, has a positive outlook, and enjoys doing their work. Increasing the number of people living healthy lives contributes to maintaining and raising the productivity of society as a whole.

Prevention is also essential to reducing the number of people who come down with illness. In that sense, I believe our business helps individual patients but it can also contribute to resolving wider social issues.

Medicine is an accumulation of knowledge. As a business, it's not the power of capital but the quality of a pharmaceuticals company's patents that makes it competitive with large companies overseas. Capital might does not determine success in the pharmaceuticals industry, nor does R&D or manufacturing capability. The key to success is the capabilities of a company's people and the expertise they bring to the production site. That is why Japan is one of only a handful of countries in the world that can produce innovative medicines.

Japan's pharmaceutical industry is going through a challenging period, and I believe we have a responsibility to transform our company so future generations can fulfill our important mission.

Message from the President

2 Strengths, risks, and opportunities

Question:

What are the company strengths that will drive its long-term growth?

Answer:

One strength is our historically proven ability to transform ourselves.

Our predecessor, Tanabe Seiyaku, was established over 300 years ago, and I believe the key to our longevity has been the ability to undergo not just one but several major transformations.

Tanabe Seiyaku originally specialized in natural remedies like Chinese herbal *kanpo* medicine but in the 1870s began offering new western medicines imported from Germany and in 1925 started mass-producing and marketing a product (salicylic acid) formulated from organic compounds. In short, the Company transformed from wholesaler of herbal medicines to a modern company offering manufactured products.

In 1974, the Company achieved its first global product through out-licensing of the hypertension treatment diltiazem (product name: Herbesser), which transformed the Company again, this time from a domestic business to a global operation. Our latest major transformation came when Tanabe Seiyaku merged with Mitsubishi Pharma Corporation in 2007. The history of our evolution makes me believe that the Group is ready for another major transformation.

I believe we need a transformation now because we are entering a whole new era with unprecedented challenges that will require the entire pharmaceutical industry in Japan to change. The government's policy to promote generic drugs has made it very difficult for pharmaceutical makers to increase profits on drugs with expired patents. On top of this economic reason, scientific advances like the advent of extremely low-cost analytic technologies, such as for the previously costly genome sequencing, and the rapid advances in digital technology, including in IoT and AI, are also compelling an industry-wide transformation.

In these conditions, whether or not we can realize our next transformation will influence the future course of the Company. In fact, we strongly feel that failing to transform the Company now will lead us to a crisis point not 30 years from now, but in just 10 years.

Transformation requires innovation. I am focusing on stimulating innovation by combining medical and digital technologies to create new hybrid medical devices. In areas where chemical expertise alone is not enough to differentiate pharmaceutical products, I believe there will be increasing opportunities to also use physic and engineering technologies, such as our devices and digital technology, to create solutions.

Consolidating our R&D bases and moving into the Shonan Health Innovation Park are two steps we have taken to stimulate innovation. The main objective of these moves is to be in contact with and integrate the latest developments arising from the explosive fusion of the computer and life sciences. We will proactively enter the open innovation space, seek promising partnerships, and form collaborations to create innovation for the medium- and long-term horizon. The pursuit of innovation will also require an internal transformation in our researchers. By expanding their sphere of contact outside traditional boundaries, our presence at the new facility will give them opportunities to broaden their perspectives.

Answer:

Another important strength is our corporate culture emphasizing trust and a desire for progress.

The core value chain for fundamental drug discovery that the Group has developed in its traditional business as a pharmaceutical company is another strength. Our drug discovery capabilities have garnered numerous awards from third-party institutions and I often receive comments that our manufacturing expertise and sales capabilities are straightforward and solid.

Upon reflection, the compliance problems we had right

after the merger are probably the reason why we are now so strong in these areas. We were adamantly determined to regain the trust that society had placed in us. Our employees should be very gratified with the results of their efforts to galvanize the whole Company to reestablish that trust. You could say that the extreme importance that we as a company place on maintaining society's trust is another of our strengths.

Another area where I think our Group stands out is the many successes we have achieved by tenaciously seeking to discover something new. For example, Remicade, which I mentioned earlier, was the first therapeutic antibody developed in Japan. We challenged ourselves to do the unprecedented: to develop an antibody drug. We didn't stop after we succeeded and marketed it. We continued our drug fostering and evolution, accumulating a growing volume of safety data and gradually adding to the indications, and it has grown into a core product with currently 13 indications.

We have also led the industry in developing drugs for incurable and rare diseases, including the Imusera (overseas: Gilenya) treatment agents for multiple sclerosis and the Radicava (in the U.S.: Radicut) treatment agent for amyotrophic lateral sclerosis (ALS). This desire to do something nobody else has done before and then to carefully see it through to the final result is in our Group's DNA.

Question:

What particularly promising opportunities does the Company see ahead?

Answer:

We believe the combination of the life sciences and digital technologies will bring major business opportunities.

As I mentioned earlier, the sharp drop in medical research costs, such as for genome sequencing, and the advances in IoT, AI, and other technologies are accelerating the integration of the life sciences and digital technology.

This fusion is behind remarkable advances in cancer treatments, and the Group wants to use it to advance treatments of immuno-inflammation. As with cancer, the effectiveness of the treatment agents changes depending on each patient's individual genetics. We believe these precision medicines whose effectiveness relies on genetic response offer a huge business opportunity. The Digital Transformation Department has been given the mission to revamp our overall business flow and also to identify and develop new business opportunities in the precision medicine field.

Question:

What major risks do you see?

Answer:

Patent expirations on new drugs present risk, but we are countering by expanding our long-tail businesses.

The new drug business carries the risk of patent cliffs, a plummet in revenue when their patents expire. We are mitigating this risk by increasing the portfolio ratio of long-tail businesses that do not rely on patents and have the potential to generate continuous revenue.

A business combining drug and a device can be a long-tail business. Insulin delivery devices are a classic example. Even after a drug patent expires, companies that market these are largely protected from competition by the barrier to developing a device, plus they generate repeat business from the need to renew the devices. Vaccines that do not have a generic alternative are another type of long-tail business. We plan to increase our weighting of drugs with devices, vaccines, and other long-tail businesses to establish a more stable revenue base.

3 Addressing ESG challenges

Question:

What is the Company's approach to ESG?

Answer:

We have specified seven material issues to address through our businesses.

The Group recognizes that fortifying its ESG activities is essential to its long-term growth. In fiscal 2018, we identified specific material issues (important social issues) based on the Sustainable Development Goals (SDGs) of the United Nations and the international guidelines of the Global Reporting Initiative (GRI) that we will focus on addressing with our businesses. In fiscal 2019, we instituted monitoring indicators that will enable management and outside entities to visually track the progress of our ESG initiatives.

Of the seven material issues, the one that we are particularly emphasizing as a pharmaceutical manufacturer is "pharmaceuticals and healthcare services with differentiated value." To become a company that can provide original value at all stages from disease

Message from the President

prevention to diagnosis, treatment, and post-treatment recovery, we plan to actively develop the pharmaceutical products in our core businesses while also offering devices and medical services as we pursue various channels to contribute to extending healthy life expectancy for people around the world.

We are also placing special emphasis on "employee health, diversity and inclusion." Maintaining an atmosphere of diversity and inclusion that encourages a diverse workforce to fully apply their abilities and expertise is essential to realizing innovation. Our internal resources, including our workforce and expertise, will not be enough to create new value. We are bringing together people with various skills and ways of thinking for maximum open innovation. Our hiring activities will also be geared to stimulating innovation by actively looking for people with various backgrounds and knowledge, mainly in the electronic devices and information and communications technology fields. Management also recognizes the qualitative importance of cultivating talented personnel for generational changeover and the succession of skilled expertise. We launched MT-VIVID, a management training program designed to begin early development of the next-generation of company leaders, in fiscal 2016 and are expanding our global evaluation process and training programs.

In addition to our social activities, we are also advancing environmental measures. Although the pharmaceutical manufacturing business generally has relatively less overall environmental impact, we are steadily reducing the energy consumption and CO_2 emissions of the Group's operations. Global warming is raising concern of an associated increase in infectious diseases, such as mosquito-borne illnesses. If infectious diseases begin to spread, the need for low-cost vaccines will also grow in all regions of the world. This has shed new light on the contribution pharmaceuticals companies that make vaccines can make to mitigating the impact of climate change, and the Group considers it to be its duty as a vaccine maker to put all our effort into developing solutions.

In the area of governance, we recognize the importance of formulating and maintaining a management structure to support our growing global business. As we prepare for full-fledged expansion of our operations in the United States, we are translating our Global Governance Policy into in multiple languages to serve our operations worldwide. We are also strengthening our compliance functions at the Group's regional headquarters in the United States, Europe, Singapore, and China. To further reinforce compliance, we plan to deeply integrate with the governance systems of each of the worldwide regional headquarters of our parent company Mitsubishi Chemical Holdings.

4 Short-term business conditions and outlook

Question:

What is the status of the medium-term management plan?

Answer:

We lowered our numerical targets, but our four strategic priorities are unchanged.

We are currently more than midway into our Medium-Term Management Plan 16–20: Open Up the Future that we launched in fiscal 2016. The plan sets four strategic priorities for growth: maximizing pipeline value, strengthening IKUYAKU (drug fostering and evolution) and marketing, accelerating U.S. business development, and reforming operational productivity. Although we remain fully committed to implementing these strategies until we achieve our target objectives, in November 2018 we revised our numerical performance targets.

The reasons for the revisions were reduced expectations

Revised Medium-Term Performance Targets

(Billions of yen)

	Fiscal 2020		Fiscal 2023
	Initial target	Revised target	
Revenue	500	430	More than 500
(of which, U.S. sales)	(80)	(40)	–
Core operating profit	100	60	More than 100

for royalty revenue, particularly from Invokana, and the slow emergence of M&A effects in the U.S. We began developing our U.S. operations with the release of the Radicava ALS treatment agent there in August 2017. However, the royalty revenues are not contributing as much to profits as we had been expecting. Also, the development of ND0612 as a treatment agent for Parkinson's disease has not progressed as we originally anticipated.

Although we revised our numerical targets, we are continuing to direct all our energies to steadily advancing the four strategic priorities. We believe that continuing to make steady progress maximizing pipeline value will lead to significant improvement in the profit contribution from the U.S. business.

Question:

What is the business outlook and what strategies will you be implementing?

Answer:

We are accelerating our transformation to generate sustained growth.

The qualitative strategy is, as described above, to continue steadily advancing the medium-term management plan. As a pharmaceutical company our drug pipeline is the main driver of our business growth. We are therefore determined to successfully bring the drugs presently in the final stages of the development pipeline to market and will continue allocate a large proportion of funds to R&D. We expect this aggressive investment spending coupled with the results of arbitration proceedings with Novartis Pharma AG to result in steep declines in our core operating profit, operating profit, and profit attributable to owners of the Company in fiscal 2019.

We are presently advancing two concrete strategies to transform the Group and accelerate the attainment of sustained growth. The first is revising our product structure by employing new modalities of increased ratios of new drug and long-tail businesses. The second is transforming our business model by adding a self-distribution business structure overseas, mainly in the U.S., to our domestic and royalty businesses. We deeply regret that will need more time to reach the targets in our medium-term management plan, yet we also believe it is necessary to shore up our strength to achieve the full and most expeditious results from our strategies. We intend to emerge from this period stronger than ever.

The history of our Group includes many periods when we overcame challenges and came out stronger. I am certain that the combined effort of our management and employees will propel us to success in this new transformation of the Company.

I look forward to the understanding and support of our shareholders as we set Mitsubishi Tanabe Pharma on a new path to the future.

September 2019

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Masayuki Mitsuka
President & Representative Director

Message from the Financial and Accounting Officer

We will steadily make needed investments for medium- to long-term growth.

Eizo Tabaru

Member of the Board,
Managing Executive Officer

Fiscal 2018 review

In fiscal 2018, domestic sales of ethical drugs decreased ¥10.5 billion year on year due to the effects of drug price revisions, a decline in long-listed drugs, the impact of the transfer of the generic drug business, and other factors.

On the other hand, sales of Radicava increased ¥14.7 billion year on year, which contributed to a ¥16.5 billion increase in overseas ethical drug sales. However, because arbitration with Novartis over royalty income began, overseas sales of ethical drugs declined ¥16.0 billion year on year mainly due to the Company not recognizing revenue in accordance with IFRS 15 on a portion of Gilenya royalties.

Although the current situation is uncertain, we will steadily proceed with efforts to successfully invest for medium- to long-term growth from fiscal 2019 and beyond.

Acquiring the ability to win in battle

The royalty business is an effective means for maximizing product value by delivering developed drugs to patients around the world. The predecessor company before merger would have faced difficulties with rapid clinical development and global market penetration even for Gilenya and Invokana, which have become profit pillars. Radicava was successful in establishing the self-distribution business in the United States, one of the challenges of the Medium-Term Management Plan 16–20. Considering the balance and risk-balance between development costs and profits, we will continue with the growth strategy of expanding the self-distribution business globally and maintaining the royalty business.

I have worked in the financial field for a long period of time and have experience setting up plants overseas and in post-merger integration (PMI). Thanks to my extensive experience working and engaging with people overseas from diverse cultural backgrounds, I was able to develop and sharpen my negotiating and decision-making skills. We are now working Companywide to develop the "ability to win" through repeated "successful experiences" such as with self-distribution in the U.S. and development overseas. Three global products positioned as growth drivers [Radicava oral suspension (MT-1186), plant-based VLP vaccine (MT-2271), Parkinson's disease treatment agent (ND0612)] and late-stage drug candidates all boast of being products with original value. In order to deliver these to patients around the world, we will rapidly gain the "ability to win" a wide range of business battles and take a giant leap forward.

Achieve medium- to long-term growth

Through the strengthening of priority areas such as Immuno-inflammation, diabetes and kidney as well as the pursuit of operational production reforms and base restructuring we expect to generate a total ¥600 billion over the five-year period from fiscal 2019–2023. Therefore, we anticipate we can fully cover shareholder returns and R&D investments.

R&D investment of ¥80 billion annually is planned for the aforementioned five-year period. Therefore, of the three global products under development, Radicava oral suspension and plant-based VLP vaccine (MT-2271) will be launched in fiscal 2021, and ND0612 will definitely finish launching in fiscal 2022. Moreover, we will advance our innovative drug candidates MT-8554 and MT-7117, which will be our new growth drivers, to late-stage development as quickly as possible.

To expand our business base in the U.S. and Europe and upgrade and expand our product lineup, we also flexibly conduct strategic mergers and acquisitions following those of Medicago and NeuroDerm. We are considering the acquisition of "investees with pipelines" that are developed and marketed using our knowhow, and "investees with products" that are already profitable in the market. We will continue to examine investments that can maximize synergies with existing business bases, including our sales system for specialty areas created with Radicava. We have set a limit for strategic investments, such as M&A, of ¥300 billion for the five years from 2019 to 2023. As of March 31, 2019, we have cash on hand of about ¥370 billion, an amount sufficient to cover our strategic investment allowance. However, ¥300 billion is not an upper limit, but merely an estimate. If we decide that a project is good and matches the above strategy, we will consider additional financing by procuring new funds.

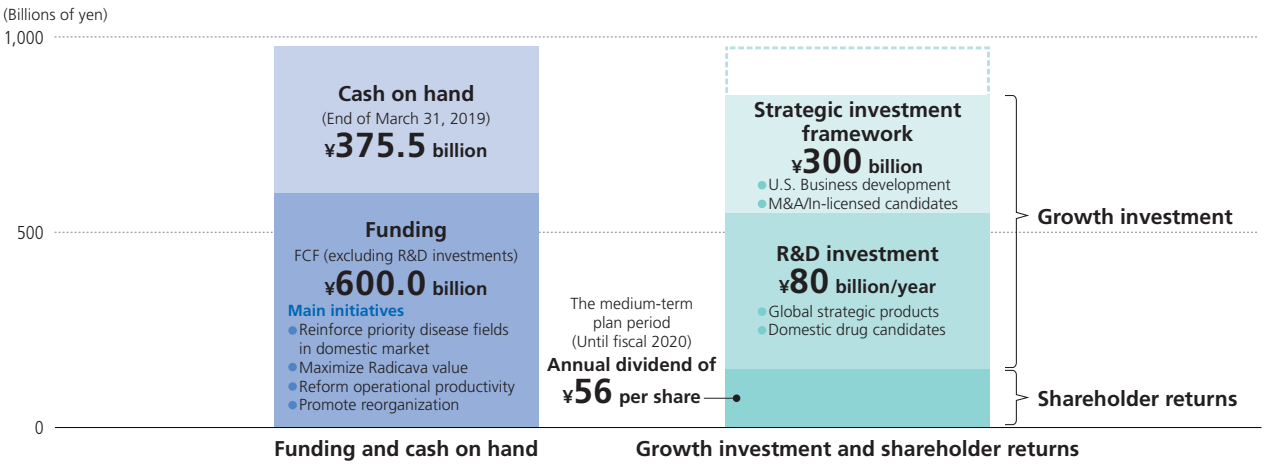
A message to shareholders and investors

The Company's basic management policy is to secure funds for sustainable growth taking into account capital efficiency to enhance shareholder returns on a stable and continuous basis. Based on this policy, we plan to pay a dividend of ¥56 per share in fiscal 2018, which we will maintain until fiscal 2020. As for the acquisition of treasury shares as a shareholder return policy, we determine the return based on a comprehensive evaluation of stock price trends, company performance, cash flow, and management environment.

In addition to the recent difficult business performance, revenue will not be recognized during Gilenya's arbitration period, so the impact could be even greater. However, that portion of revenue that is not recognized will be recognized in lump sum depending on the arbitration results. We will also push forward to achieve the medium-term management plan, which was revised in November 2018.

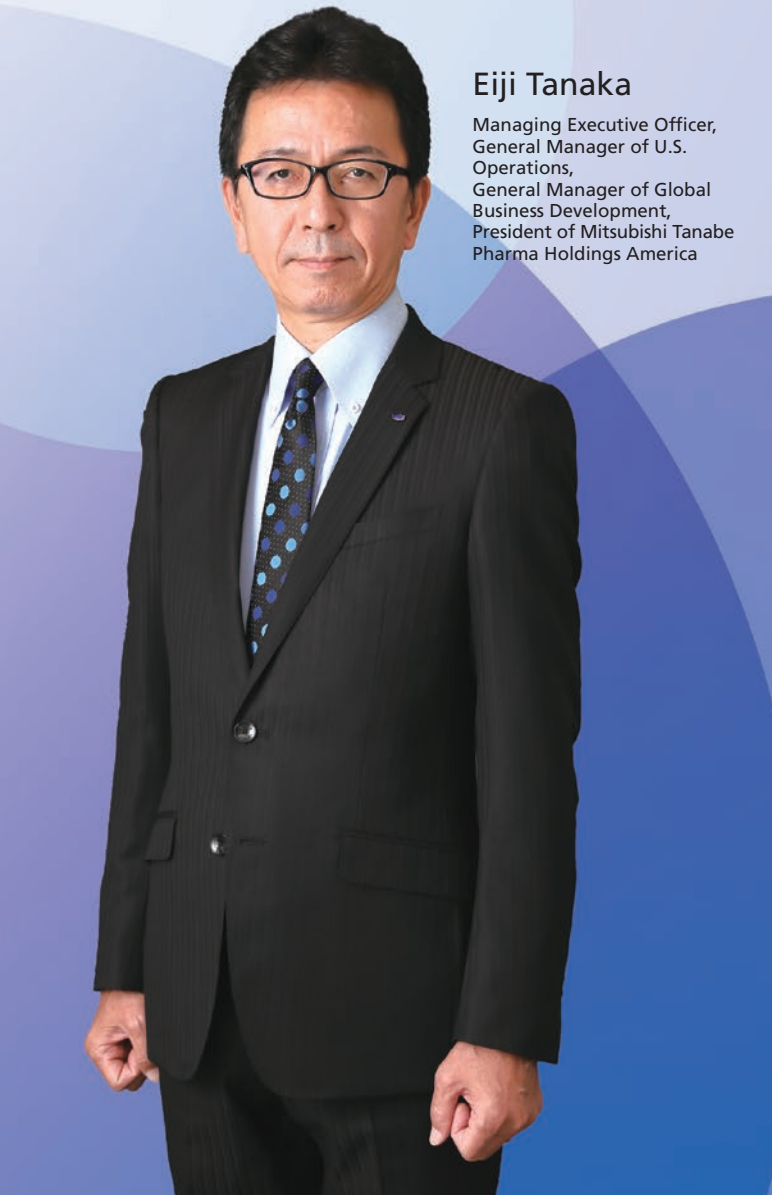
Due to the nature of arbitration, many shareholders may feel uneasy by the lack of explanation provided to everyone, but pipeline development and important strategies, including the promotion of overseas business, are steadily progressing with the aim of medium- to long-term growth. We hope you will look forward to the dramatic growth we have planned for the future, and we ask for your continued support.

Growth investments and shareholder returns (fiscal 2019 – 2023)



U.S. Business

We are implementing three deliberate steps to establish sustained growth in the world's largest pharmaceuticals market.



Eiji Tanaka

Managing Executive Officer,
General Manager of U.S. Operations,
General Manager of Global Business Development,
President of Mitsubishi Tanabe Pharma Holdings America

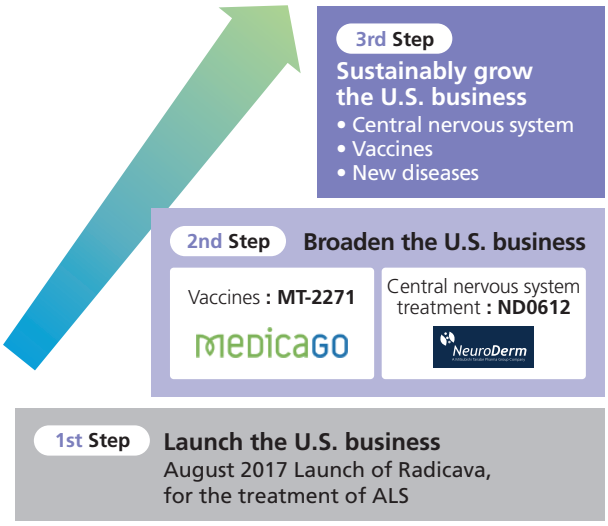
Basic policy

Expanding our business in the United States, which is by far the world's largest market for pharmaceuticals, is absolutely essential to fulfilling the goals of our Medium-Term Management Plan 16–20 and to achieving sustained growth.

The roadmap for establishing the U.S. business and generating sustained growth has three steps: launch, broaden, and sustainably grow. We will launch the U.S. business by introducing the ALS treatment agent Radicava to the market. Then we will broaden the business by aggressively investing in strategic areas. And finally, we will build on the first two steps to construct a business foundation for continual growth centered on in-house products.

We have already made progress with the first two steps under the medium-term management plan. Radicava was released in August 2017, and we invested ¥124 billion ($1.1 billion) to acquire and make a full subsidiary of NeuroDerm in October 2017.

We are also preparing to release the MT-1186 Radicava oral suspension and MT-2271 plant-based virus-like particle (VLP) seasonal influenza vaccine in fiscal 2021, followed by NeuroDerm's ND0612 treatment for Parkinson's disease in fiscal 2022. We expect these three products to be strong growth drivers and generate accelerated growth. Through these activities we will increase our presence in the U.S. market and firmly advance us to the third stage of establishing sustained business growth centered on our proprietary products. We will continue developing the U.S. business to make it the Company's second main earnings source behind our domestic operations.



Overview of the U.S. business

Mitsubishi Tanabe Pharma America (MTPA), which handles sales and marketing functions in the United States, executed the first step of our plan to launch the U.S. business with the August 2017 sales release of Radicava. MTPA has been improving the treatment environment and conducting biomarker trials to acquire new data to pave the way for a successful market launch in fiscal 2021 and maximize sales of Radicava. MTPA is also preparing to market the plant-based VLP vaccine being developed by Group company Medicago, of Canada, which will advance the second strategic step of broadening the U.S. business. The Parkinson's disease treatment ND0612 is also being developed by NeuroDerm.

Mitsubishi Tanabe Pharma Development America (MTDA) is also playing a central role in the Group's global aspirations. MTDA is developing the Radicava oral

Achieving success developing global pharmaceutical products

Mitsubishi Tanabe Pharma Development America (MTDA)

Hideki Kuki
President

Radicava sales in the United States have been steadily growing since the drug was introduced in August 2017. MTDA has been tenaciously supporting the Radicava business to succeed, including submitting a request after obtaining marketing approval to change a part of the approval details, managing safety information, and applying for and receiving authorization to market Radicava outside the United States. At the same time, it is leading the clinical research of the in-house developed MT-1186 oral agent.

MTDA has the important mission to follow-up the success with Radicava by developing new drug products for the global market to maximize pipeline value, which is one of the four strategic priorities in the Medium-Term Management Plan 16–20. The MTPC Group has assembled development project teams from its member companies, which is working closely with each company's functional organizations and related departments to plan and execute drug development projects for global markets.

MTDA has a highly efficient and effective operating structure that outsources the majority of clinical study operations so it can focus primarily on forming and managing drug development plans, regulatory affairs strategies, and safety risk assessments. With the increasingly strict requirements from regulatory authorities and demand from medical society, new drug development must take medical economics into account. MTDA is also playing a crucial role constructing a network of experts in various fields in the United States, Europe, and Japan that will raise the probability of success of our drug development activities while ensuring we accurately fulfill both the medical and economic needs. We remain dedicated to the full process of bringing new drugs to market starting with combining knowledge from inside and outside the Company, establishing project proof of concept at an early stage, steadily advancing drug development to the final stages, and successfully obtaining marketing approval.

U.S. Business

suspension and is advancing the in-house production of drugs for the third step to sustainably grow the U.S. business. The company has generated several projects with global potential and is contributing to strengthening the drug pipeline for the Group's future growth.

Expanding our business in the U.S. market, which is expected to remain the world's largest pharmaceuticals market, is essential to achieving sustained earnings growth for the Group.

Progress with the three steps

As mentioned above, after the first step to establish the U.S. business by releasing Radicava, we are now moving to launch the oral preparation and implement measures to maximize sales.

The second step is to continue preparing for the release of Medicago's plant-based VLP vaccine, for which we are aiming to receive approval in fiscal 2021, while also advancing the development of NeuroDerm's Parkinson's disease treatment ND0612 for a target release date in fiscal 2022.

The key tasks for the third step will be to formulate the operating structure and implement measures to establish ongoing growth for fiscal 2021 and beyond. That will require careful selection and concentration of investment in R&D with the clear aim of bringing in-house developed products to market as swiftly as possible.

Mitsubishi Tanabe Pharma Holdings America (MTHA) conducts market analysis to accurately identify the needs of patients and healthcare professionals. The company also contributes to developing strategies from the market's perspective by proposing market access strategies to construct compelling evidence to gain the backing of insurers and ultimately to enable access to all patients considered in need of the new drugs.

These activities are all geared to enhancing our ability to discover drugs matched to market needs and seamlessly progress to formulating marketing strategies while also accelerating in-house drug development to maximize the value in our drug development pipeline. MTHA is also strengthening the management infrastructure, including reinforcing governance and ensuring comprehensive compliance at companies doing business in the United States, which is essential to maintaining sustained business growth.

Growth drivers

(1) Radicava

Since the release of Radicava, MTPA has been providing educational opportunities about ALS and Radicava to the primary stakeholders of patients, doctors, and insurers and seeking to increase the number of medical institutions where Radicava is available to improve treatment options for ALS patients. As of June 2019, these efforts have helped increase the number of ALS patients benefiting from treatment using Radicava to over 4,000 people.

While continuing these activities, we will also seek to improve the ALS treatment environment and lay the groundwork for the release of the oral treatment in fiscal 2021 by increasing recognition of Radicava among

ALS Biomarker Research

Mitsubishi Tanabe Pharma America (MTPA)

Stephen L. Apple, MD
Senior Medical Director

Biomarkers are biological substances such as proteins or genes that may play a role in the diagnosis or prognosis of a disease, Biomarkers may also play an important role as indicators of treatment effectiveness. Biomarkers are attracting particular attention from healthcare professionals involved in amyotrophic lateral sclerosis (ALS) treatment and research as well as ALS patient communities. MTPA is collaborating in a study with Massachusetts General Hospital to identify and measure specific biomarkers in roughly 300 people using Radicava to treat ALS. The study, which is being conducted at roughly 40 sites in the United States, will seek to create a panel of biomarkers that may be associated with Radicava treatment in ALS, including those for oxidative stress, inflammation, muscle and neuronal injury and death.

We hope this research will deepen our understanding of how Radicava affects the progression of ALS. The companies participating in the collaboration each bring unique evaluation techniques. As part of the collaboration, MTPA in the United States conducted its first clinical research of biomarkers, which was an important milestone for our business. We are proud to be leading this research and to be able to come together with members of the ALS community. In 2019, the study plans to enroll patients to participate in the biomarker study, and we plan to conduct the first interim analysis by the end of the year.

healthcare professionals to promote effective use, creating environments conducive to prescribing it, and facilitating patient accessibility to it for treatment. Because the Radicava oral suspension will be much easier to administer than the current method of intravenous drip infusion, it will widen the scope of patient eligibility, which will both address unmet medical needs and maximize the value of the treatment.

(2) VLP Vaccine

Medicago is a biopharmaceutical company specializing in the research and development of new vaccines using plant-based virus-like particle (VLP) technology. VLP vaccines have the potential to provide strong and extremely safe protection against viruses. Because the external structures of VLPs resemble viruses, they stimulate the body's immune system but carry no threat of viral transmission because they contain no viral genetic material. VLP vaccine technology also offers the significant advantages of being less costly and quicker to manufacture than current vaccines.

Medicago has proprietary technology to grow VLPs in plant cells and efficiently extract and refine the VLPs. The company completed phase 3 testing of its seasonal flu VLP vaccine for adult patients in the United States and Canada during the 2017-2018 influenza season. In fiscal 2019, the company is expecting to receive the results of phase 3 trials for administering the flu vaccine to elderly patients in the second quarter and plans to apply for approval in the United States for administering the vaccine to adults in the same year with the objective of beginning sales in fiscal 2021.

(3) ND0612

NeuroDerm has proprietary production technology for liquefying insoluble compounds. The company is using its "designed pharmaceuticals" combining pharmaceuticals and devices to increase drug effectiveness and is also advancing development of ND0612, its Parkinson's disease treatment formulated to reduce side effects. There are estimated to be over a million people with Parkinson's disease in the United States alone, and the research and development of the ND0612 treatment has high clinical value for its potential to meet a vast worldwide unmet medical need.

The development plan for ND0612 had been under review but in fiscal 2018 the company and the United States Food & Drug Administration (FDA) discussed and reached a general agreement on the design of Phase 3 study. The company plans to simultaneously submit approval applications in Europe and the United States in fiscal 2021 with the aim of beginning sales in fiscal 2022.

Business Strategies by Process

Drug Discovery

Focus on expanding the pipeline and promoting open innovation

Yoshiharu Hayashi
Executive Officer,
Head of Sohyaku.
Innovative Research Division

Basic policy

The Sohyaku. Innovative Research Division strives every day to continually discover new drugs for the world that address unmet medical needs with the aim of becoming a "pharmaceutical company working with a sense of speed to be the first to deliver original value."

In the area of diseases, the Company is focused on the priority areas of central nervous system diseases and immune-inflammation diseases. At the same time, we are working on additional new areas and modalities for the future and will identify the ones that will become our next pillar of business.

In drug discovery activities, we are aggressively promoting cooperative business through industry-academia-government collaboration and using external drug discovery resources to expand these discovery opportunities, such as identification of novel targets and technologies.

Fiscal 2018 summary and fiscal 2019 initiatives

In fiscal 2018, we sought to rapidly obtain PoC for our drug candidates and focused on strengthening translational research[1]. One of the results is that we selected highly unique indications in several projects, which enabled us to advance the candidates to Phase 1. As we promote the diversification of modalities, we seek to expand our research pipeline to achieve the continuous creation of development candidates.

In addition, with respect to our drug development project, a collaboration with our pharmaceutical development subsidiary in the U.S., Mitsubishi Tanabe Pharma Development America, and in Europe, Mitsubishi Tanabe Pharma Europe, was able to drive the PoC study for its first product as planned after the establishment of our global development system.

Meanwhile, an issue in fiscal 2018 was that we were unable to create drug candidates in priority areas, particularly central nervous system diseases and immuno-inflammation diseases that lead to internal sales, especially in the U.S. following Radicava. It is necessary, more than ever before, to rigorously promote projects from a translational research perspective from the initial stage of research. Another issue was that the results of open innovation in basic research did not effectively lead to pipeline expansion.

In light of these issues, we will continue to steadily promote PoC studies and aggressively expand our pipeline focusing on priority areas in fiscal 2019. Furthermore, our policy is to focus on opening up the research environment. We created an environment where new synergies are easily produced, such as the Shonan Health Innovation Park

(see page 32), and we will collaborate with the best partners inside and outside the Company and incorporate leading-edge technologies. Moreover, we will encourage open discussions on new themes and ideas in the Sohyaku. Innovative Research Division and promote transparency in budget and human resource allocation. In addition, we will strengthen the connection between clinical practice (medical) and basic research (science) by collaborating with the Ikuyaku. Integrated Value Development Division. In cooperation with physicians inside and outside the Company, we will push forward with highly relevant project management that incorporates medical needs and a medical perspective from the early stages of research.

1. "Translational research" involves the connection from basic research to clinical practice. Its purpose is to bridge the excellent results obtained from basic research at universities with the development of innovative pharmaceuticals.

Medium- to long-term perspective

To achieve the goals of the Medium-Term Management Plan 16–20, the Sohyaku. Innovative Research Division should first focus on swift PoC confirmation of drug candidates and pipeline expansion through the continuous creation of drug candidates with a focus on priority areas. Continued discussions on the expansions of the pipeline are to be carried out, not only within the Sohyaku. Innovative Research Division, but also in joint effort with "Drug Discovery Strategy Team" set up in collaboration with the Global Portfolio Management Department and other departments.

The Sohyaku. Innovative Research Division's long-term goal is the "continuous creation of original drug candidates that meet future medical needs." Our strength lies in our drug discovery capabilities. We have a track record of creating the world's first unique pharmaceuticals leveraging our capabilities in chemical synthesis. In addition to conventional small-molecule drug discovery, we are also now expanding new modalities such as nucleic acid drugs and middle molecule drug discovery. Our ideas, creativity and tenacity for creating highly original products are also our strengths.

On the other hand, we need to accelerate drug discovery more than ever. To that end, one thing we should do is to streamline decision-making. In the initial stage of research, we need to emphasize taking on challenges and to not take too much time gathering information for streamlined decision-making. Furthermore, we believe that we can accelerate the entire drug discovery process by incorporating external knowledge and technologies through open innovation and better leveraging external assets. For example, as a new challenge that leverages open innovation, we are conducting drug discovery research on gene therapy in collaboration with Jichi Medical University.

Arisa Hisanaga
Research Unit/Neuroscience, Sohyaku. Innovative Research Division

Develop reliable assay systems and basic technologies to challenge new themes with high medical needs

I was attracted by this work, drug discovery, that can contribute to the health of people around the world, so I studied brain and nerve functions at the faculty of pharmaceutical sciences during my university days. Since joining the company, I have been consistently engaged in central nervous system projects and primarily responsible for developing assays for compounds.

Before a new drug can be made, the cycle of (1) evaluating the compound and (2) synthesizing the compound based on those results must be repeated to improve the efficacy of the compound. Establishing an assay system that enables us to generate highly recapitulated results is critical to effectively repeat this cycle.

Recently, we created an assay utilizing iPS cell-derived neurons. iPS cells are relatively unstable and it was difficult to obtain highly reproducible results compared to the cells that we have dealt with so far. However, as a result of trial and error based on the advice from other members and my supervisors, I could successfully set up a stable assay, which now contributes significantly to the efficient progress of current drug discovery projects. Moving forward, I'd like to take part in developing functional assays that use patient-derived cells with the aim of discovering pharmaceuticals that can further help patients.

Currently, I'm investigating new projects as a member of the Neuroscience Research Unit. In the field of central nervous system, there are many serious diseases for which treatment has not yet been established despite significant needs from patients, their families, and medical professionals. To address those needs, I'm now conducting validation experiments on new concepts targeting ALS and other neurological diseases. I interact with US doctors and constantly study day after day while assimilating the latest information from domestic and overseas academic conferences and various papers.

I will continue to take on challenging themes that help us develop new pharmaceuticals while enhancing my expertise, and make every effort to improve our own drug discovery infrastructure from a long-term perspective so that I can contribute to the health and happiness of people around the world.

Business Strategies by Process　Drug Discovery

It is also important to create a better environment for creating such innovations. We will create a more open research environment and promote collaboration with the best partners inside and outside the Company. The relocation of our research laboratory to Shonan Health Innovation Park in the current fiscal year is also viewed as laying the groundwork for pursuing this open innovation.

Furthermore, we also need to change researchers' way of thinking to challenge diseases with high unmet medical needs. We hope to generate new ideas by encouraging researchers who tend to stay in their own shells to break out and expand their perspectives and ideas through opportunities for dialogue and discussion with outsiders. I believe that creating a corporate culture that encourages taking on challenges is a vital mission as Head of the Sohyaku. Innovative Research Division.

Possible risks and countermeasures

Generally speaking, ideas that anticipate future needs, such as what drugs will be needed 10 years from now or ascertaining trends in diseases and technologies are highly important in drug discovery with a long development lead time, and misreading trends could be risky. Research and evaluation of disease trends is being led by three drug discovery units, and technology trends by Modality Laboratories and the US research subsidiary Tanabe Research Laboratories U.S.A. We are proceeding with development for early commercialization of VLP vaccines, a new modality, in collaboration with Medicago and products that combine pharmaceuticals and medical devices in collaboration with NeuroDerm.

On the other hand, there are risks related to the development of new modalities and risks related to regulatory controls and drug price revisions by relevant authorities. With regard to these, we will closely monitor the international situation and industry trends, and take steps to reduce risks through prior consultations with relevant authorities.

Message to shareholders and investors

I think that many of our personnel thrive on adversity, understanding the true nature of problems and finding solutions by themselves. To create pharmaceuticals and medical services that offer new value by leveraging these personnel, we will integrate the individual strengths of each person in the Sohyaku. Innovative Research Division and continue to create original products that meet future medical needs.

Accelerate open innovation by leveraging Shonan Health Innovation Park

As initiatives for Medium-Term Management Plan 16–20 and beyond that toward fiscal 2023, we are reexamining the allocation of management resources, optimizing and streamlining our global management system, and reinforcing each function.

As part of this, to accelerate open innovation in drug discovery research, we decided to use the Shonan Health Innovation Park in Kanagawa Prefecture as one of the research centers starting from May 2019. The Company will swiftly and powerfully take on the challenge of addressing new technologies, new treatments, and new disease areas in this park.

In addition to pharmaceutical companies and drug discovery ventures, the Shonan Health Innovation Park is occupied by companies that provide drug discovery support services, research and medical devices, and are engaged in AI and IoT business, and the park is working to attract more such companies. Approximately 250 researchers working in the Frontier Research Unit, the Modality Laboratories, and other facilities from the Yokohama Office, the Toda Office (closed in fiscal 2019) will move in to expand collaboration opportunities by building a human network with existing tenants. Above all, we will pursue initiatives based on the theme of achieving radical treatments using genetic drug discovery, which will lead to the provision of new pharmaceuticals and medical services for the prevention and cure of rare and intractable diseases.

Business Strategies by Process　Pipeline

Status of drug candidates (as of July 25, 2019)

Asia: excluding Japan and China

Development code Product name (Generic name)	Category	Indications	Region	Stage Phase 1 2 3 / Filed	Origin
Immuno-inflammation					
MT-5547	Fully human anti-NGF monoclonal antibody	Osteoarthritis	Japan	Phase 2/3	US: Regeneron
MT-1303	S1P receptor functional antagonist	Multiple sclerosis	Europe		In-house
		Crohn's disease	Japan		
MT-7117	Dermatologicals, etc.	Erythropoietic protoporphyria	Global		In-house
MT-2990	Fully human anti-interleukin-33 (IL-33) monoclonal antibody	Endometriosis	Global		In-house
		Seasonal Allergic Rhinitis	–		
Diabetes and kidney					
TA-7284 **Canaglu** (Canagliflozin)	SGLT2 inhibitor	Type 2 diabetes mellitus	Asia		In-house
		Diabetic nephropathy	Japan		
MP-513 **Tenelia** (Teneligliptin)	DPP-4 inhibitor	Type 2 diabetes mellitus	Asia		In-house
			China		
			Europe		
MT-6548 (Vadadustat)	Hypoxia inducible factor prolyl hydroxylase inhibitor	Renal anemia	Japan	19.07	US: Akebia
MT-3995	Selective mineralocorticoid receptor antagonist	Diabetic nephropathy	Europe		In-house
			Japan		
		Non-alcoholic steatohepatitis: NASH	Japan		
Central nervous system					
MCI-186 **Radicut/Radicava** (Edaravone)	Free radical scavenger	Amyotrophic lateral sclerosis: ALS	China	19.04	In-house
			Asia		
MP-214 (Cariprazine)	Dopamine D3/D2 receptor partial agonist	Schizophrenia	Asia		Hungary: Gedeon Richter
MT-5199	Vesicular monoamine transporter type 2 inhibitor	Tardive dyskinesia	Japan	Phase 2/3	US: Neurocrine Biosciences
MT-8554	TRPM8 antagonist	Painful diabetic peripheral neuropathy	Europe		In-house
		Vasomotor symptoms associated with menopause	Global		
ND0612 (Levodopa/Carbidopa)	Continuous SC pump/ patch pump	Parkinson's disease	Global		In-house
ND0701 (Apomorphine)	Continuous SC pump	Parkinson's disease	–		In-house
MT-1186 (Edaravone)	Free radical scavenger	Amyotrophic lateral sclerosis: ALS/Oral suspension	–		In-house
MT-6345	Nervous system	–	–		Japan: Co-developed with Ube Industries
MT-3921	Anti-RGMa antibody	Spinal cord injury	–		Japan: Co-developed with Osaka University

Asia: excluding Japan and China

Development code Product name (Generic name)	Category	Indications	Region	Stage (Phase 1 2 3 / Filed)	Origin
Vaccines					
MT-2355	Combined vaccine	Prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis and prophylaxis of Hib infection in infants	Japan		Japan: Co-developed with The Research Foundation for Microbial Diseases of Osaka University
MT-2271	Plant-based VLP vaccine	Prophylaxis of seasonal influenza/adults	US, Europe		Canada: Medicago product
		Prophylaxis of seasonal influenza/elderly	US, Europe		
MT-8972	Plant-based VLP vaccine	Prophylaxis of H5N1 influenza	Canada		Canada: Medicago product
MT-7529	Plant-based VLP vaccine	Prophylaxis of H7N9 influenza	–		Canada: Medicago product
MT-5625	Plant-based VLP vaccine	Prophylaxis of rotavirus gastroenteritis	–		Canada: Medicago product
Others					
TAU-284 Talion (Bepotastine)	Selective histamine H1 receptor antagonist, anti-allergic agent	Allergic rhinitis, Urticaria	Asia		Japan: Licensed from Ube Industries
MT-4129	Cardiovascular system, etc.	–	–		In-house

Major out-licensed products

Development code Product name (Generic name)	Category	Indications	Region	Stage (Phase 1 2 3 / Filed)	licensee
Diabetes and kidney					
TA-7284 INVOKANA (Canagliflozin)	SGLT2 inhibitor	Diabetic nephropathy	US	19.03	US: Janssen Pharmaceuticals
Central nervous system					
MT-210	5-HT2A/Sigma 2 receptor antagonist	Schizophrenia	US, Europe		US: Minerva Neurosciences
Others					
MT-4580 Orkedia (Evocalcet)	Ca sensing receptor agonist	Hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism	Japan	19.04	Japan: Licensed to Kyowa Kirin

Business Strategies by Process

Drug Fostering and Evolution

Maximize and optimize pharmaceutical value in global development

Yoshihiro Kobayashi

Member of the Board, Managing Executive Officer,
Head of Ikuyaku. Integrated Value Development Division

Basic policy

The Ikuyaku. Integrated Value Development Division features the development section that plans and manages clinical trials for pharmaceuticals, the medical affairs section that is responsible for medical activities such as the acquisition and dissemination of various information required in medical settings, and the pharmacovigilance (PV) section that conducts surveys and writes reports on safety information and drug side effects and also oversees a wide range of functions including the data science section that makes use of clinical trials, PV data, and RWD[1] to extract scientifically and socially useful information. With these various specialized sections collaborating together, we strive to maximize product value in various stages, from late development to post-marketing, centered on our priority disease areas of immuno-inflammation, diabetes and kidney, central nervous system, and vaccines.

1. The acronym for Real World Data, which refers to data that is based on actual medical care practices, such as medical fee data (health insurance claim receipts) and medical exam data, or the databases of these.

Fiscal 2018 summary and fiscal 2019 initiatives

In fiscal 2018, this division pursued initiatives based on the themes of "Late-stage drug development in Japan and Asia," "Medical activities for diabetes centered on Canaglu and Tenelia," and the "Global promotion of PV activities."

Notably, in "Late-stage drug development in Japan and Asia," development of MT-6548, MT-5547, MT-5199, TA-7284 (diabetic nephropathy), and MP-513 (China) proceeded without a hitch. Of these, MT-6548 and MP-513 (China) achieved the primary endpoints anticipated in Phase 3 and are moving steadily ahead to launch as new drugs. In addition, we gave academic presentations and presented papers on the results of various clinical studies and post-marketing surveillance in collaboration with the medical affairs and PV sections. Among these, an interim report we presented on the results of Radicut use in ALS received the Excellence Award from the Japanese Society of Neurological Therapeutics.

In fiscal 2019, we will focus on "Pipeline enhancement and selection," "Acceleration of development," and "Streamlining operations" as priority issues. In our development work, we will apply for approval of MT-6548 in Japan, which obtained Phase 3 results in fiscal 2018, and approval of MP-513 in China, and move forward with other drug candidates according to plan. Since MT-8554 and MT-7117, which originated in-house, will enter the global late-stage development phase as drug candidates, in the development of these and Radicava oral suspension (MT-1186) in Japan and Asia, we will promptly cooperate with medical and PV activities to promote integrated global

activities. As for diabetes and kidney disease, Janssen Pharmaceuticals, a U.S. company, presented the excellent results of a clinical study of diabetic nephropathy (CREDENCE study[2]) at an international conference in April 2019. Consequently, we will strengthen our development and medical activities in Japan to quickly deliver these results in Japan as well.

2. Acronym for Canagliflozin and Renal Events in Diabetes with Established Nephropathy Clinical Evaluation.

Medium- to long-term perspective

New modalities such as regenerative medicine, gene therapy, and digital medicine are emerging in the medical world. Moreover, past rules and methods are changing, for example, "global development" now occurs simultaneously at locations around the world, and RWD and AI being used. In anticipation of these changes, as a global research-driven pharmaceutical company, we will continue to work with Sohyaku. Innovative Research Division and overseas affiliates to provide society with new drugs that patients around the world are eagerly waiting for, and we will continue to increase their value.

In maximizing and optimizing the value of pharmaceuticals, drug applications and approvals are only "waypoints." We are carrying out our activities with greater determination to further enhance and optimize their value, including development activities such as adding indications, medical activities by providing medical information for clinical questions[3], and PV activities such as collecting post-marketing safety information. We have built a system which enables the development, medical affairs, PV, and data science sections to promote strategies through this division, and with this we are steadily accumulating a wide range of knowledge and experience. Moving forward, we will continue to leverage all of these to maximize and optimize the value of pharmaceuticals not only in Japan and Asia, but globally. Furthermore, we seek to enhance our expertise and streamline operations by strengthening not only the expertise of each department's operations, but also collaboration in disease areas including priority diseases.

3. Clinical questions and issues. There are of various types including those related to clinical condition, evaluation, treatment, risk, and prevention.

Message to shareholders and investors

One risk that is becoming apparent is the global rise in R&D costs. On the other hand, market conditions for pharmaceuticals have become increasingly harsh due to the promotion of cost control measures in Japan and other countries. We need to consider how quickly we can deliver treatment agents and treatment methods that society urgently requires without being bound by past methods.

This division will create new methods that are focused on patient-centered healthcare. I would like to create a system that enables the efficient turning of the PDCA cycle and lets us quickly determine and select those things that are certain from those that are not. For example, Japan is expected to be the first country in the world to approve and launch MT-6548, which is now under development, and post-marketing safety information that we collect will be disseminated worldwide in the future. It is important to quickly collect and analyze safety information immediately after sales and appropriately disseminate it worldwide. Since it is important that we strengthen our global system in the United States and worldwide, we will train employees to have a broad and multifaceted perspective. Recognizing that we are globally connected wherever we are, we will act based on our key message of "Think globally, Act locally."

Along with changes in the business environment, each department of this division will increasingly require a high level of specialization. In addition to drug development activities in Japan and Asia, we will work closely with the functions of each department to expand the Group's business presence around the world.

Business Strategies by Process

Supply Chain

Promote rebuilding of supply chain system to adapt to changes in the business environment

Ryosuke Tanabe
Executive Officer,
Head of Production Technology &
Supply Chain Management Division

Basic policy

The Production Technology & Supply Chain Management Division was established in April 2018 with the integration of the CMC[1] Division and the Production Division. It plays a role in facilitating and flexibly promoting *monozukuri* (manufacturing with production technology and supply chain management), from the manufacture of investigational drug products used in clinical trials to product design for launch, commercial product procurement, production and supply.

In fiscal 2019, we will steadily promote development projects and maximize product value through product design from the customer's point of view. At the same time, we will restructure our Japan-centered *monozukuri* system into a system capable of adapting to our U.S.-centered business development.

1. CMC: The acronym for Chemistry, Manufacturing and Control ("the chemistry, manufacturing and quality control of drug ingredients and pharmaceuticals"). Comprehensive research that supports pharmaceutical manufacturing and quality.

Fiscal 2018 summary and fiscal 2019 initiatives

In fiscal 2018, when our division was established, we formulated a plan for restructuring our production and technology bases under our "Strategic Future Vision for Production, SCM[2], and CMC." In fiscal 2019, the steady implementation of this restructuring plan will be a priority issue.

For example, this restructuring plan will include factors such as further strengthening of our capabilities in the field of global supply chain management. Leveraging the experience and know-how gained from Radicava, we will create a system that enables rapid supply of globally developed products such as MT-1186, ND0612, MT-8554, and MT-7117, from investigational drug products to commercial product supply.

In addition, we will leverage the characteristics of our domestic production bases to achieve an efficient production system. Based on the product life cycle, the Onoda Office will be responsible for everything from the manufacture of investigational drugs to the timing of their introduction and growth, while the Yoshitomi Office will promote the reallocation of production items following the restructuring of production bases, and will changeover to a system that supports *monozukuri* from growth period onward, and provides efficient and stable supply.

Furthermore, we will rebuild our production technology to create unique value and deliver it globally. To achieve a seamless connection between CMC and production functions, a new research building, CMC Innovative Laboratories (CIL), will be constructed at the site of the Onoda Office and develop it as a *monozukuri*

base. In addition, technology and know-how not located in-house will be acquired through partnering including collaboration with industry, academia, and government.

2. SCM: Acronym for Supply Chain Management. A business management method for optimizing the entire process from raw material procurement to manufacturing and supply to consumers.

Medium- to long-term strategy

The mission of our division is to grasp the needs of the market, rapidly create the products that are needed, and stably deliver products of both reliable quality and reasonable cost to customers around the world based on our high technological capabilities.

As typified by the three growth drivers, we need to shift not only investigational drugs, but also our product supply system to the U.S. to accompany the shift of development and sales areas to the U.S. Along with these changes, the functions of our division must be changed, and therefore we will build the systems that we need in the future.

To contribute to the company's global growth, we will also focus on the early development of human resources who can properly build and manage supply chains, who can manage positive relationships with various stakeholders, and who can properly respond to new modalities and markets.

A message to shareholders and investors

While raw materials suppliers, manufacturing sites, and sales regions of pharmaceuticals have globalized, global products have to be supplied according to different regulations and local requirements for each country, so it is increasingly difficult to demonstrate economies of scale by manufacturing one product together from a supply chain perspective.

In addition, manufacturing sites with special raw materials and technologies required for new modalities are limited, and there may be risks that could affect stable supply due to unexpected natural disasters and accidents. As countermeasures to these risks, we have developed rules and manuals for responding to crises with a view to business continuity, and have identified specific risks for each key business in the supply chain.

Because the market, patient needs, and required technologies are constantly changing, we will strengthen *monozukuri* from the customer's point of view and create a supply chain system that adapts to changes in the business environment so as to achieve "reliable products and sustainable supply," one of our material issues.

Takashi Nishii
Technology Department, Yoshitomi Plant
Mitsubishi Tanabe Pharma Factory Ltd.

Viewing the reorganization as an opportunity, we will introduce new technologies while ensuring quality

The Group is currently reorganizing its bases with the aim of establishing a global new drug supply system and switching to a flexible and efficient production system that is resistant to environmental changes. Accordingly, I'm in charge of transferring manufacturing technology between factories and outside the Company, and every day I feel how difficult it is to transfer manufacturing technology and continue to manufacture products of the same quality as if it were nothing. Complex factors such as raw materials, machinery, and manufacturing environment may affect quality, even in the same process and procedure. Moreover, the transfer of manufacturing technology substantially changes manufacturing conditions, so high technology is required to ensure the same quality.

For example, when the technology used to manufacture a tablet at our plant was transferred to a new plant, the brand name printed on the tablet was changed to appear on both sides instead of just one, and as a result, many technical issues needed to be solved. Therefore, working closely with the manufacturing division, we reviewed the process from the beginning and conducted repeated trial and error, such as changing the method used to polish the tablet surface. As a result, we not only ensured quality, but were able to achieve significant reductions in work time and defect rate. In a situation that requires close collaboration with other departments and related companies, we reaffirmed the importance of leading the project by having our technical staff carefully examine a wide range of information. Furthermore, viewing each change as an opportunity to achieve a higher quality, lower cost, and more stable supply than before, we review data analysis at the time of the manufacturing technology transfer. At the same time, we are actively introducing new technologies such as non-destructive and non-contact analysis technologies and continuous monitoring methods.

Also, to improve my expertise and acquire further problem-solving skills, I'm registered as a visiting researcher at a university under a work-study program. I will further enhance cooperation between the production and research divisions while combining the experience gained at the Company and the knowledge learned at the university so that we can manufacture and provide even safer and more secure pharmaceutical drugs than before.

Business Strategies by Process

Marketing

Providing high value-added information through consulting and solutions

Yasutoshi Kawakami

Executive Officer,
Head of Sale &
Marketing Division

Basic policy

The pharmaceutical market in Japan continues to face a tough environment due to drastic reform of the drug price system. Furthermore, with the introduction of "Sales Information Provision Activity Guidelines," regulations concerning MR activities have been tightened. Under these market conditions, the Sales & Marketing Division will prop up the Company's growth foundation with the goal of maintaining revenue of ¥300.0 billion in Japan.

In fiscal 2019, we will take area marketing and digital marketing to new levels and strengthen prescription proposal capabilities, which were priority policies in fiscal 2018. We will also maximize our presence in existing areas and prepare to launch new drugs.

Fiscal 2018 summary and fiscal 2019 initiatives

One of our achievements in fiscal 2018 was to raise our market share through area marketing. Area marketing planners (AMPs), who are deployed in all sales offices, played a central role to boost the market share of Canaglu, Tenelia, and Canalia for diabetes and kidney diseases by drawing up and executing strategies for each area. In digital marketing, in response to the growing number of multichannel customers, doctor assessments have dramatically boosted our ranking[1] from No. 20 last year to No. 8 this year thanks to our healthcare professional website Medical View Point and MR activities that effectively used digital marketing tools. Finally, with regard to strengthening our prescription proposal capabilities, in the area of immuno-inflammation, Remicade, Simponi, and Stelara maintained the No. 1 market share[2] and MR activity evaluations boosted the Company from No. 7 last year to No. 6 this year in the area of diabetes[3].

In light of the impact of the Sales Information Provision Activity Guidelines and Promotion of Working Style Reforms for Healthcare Professionals, in fiscal 2019, we recognize the need to provide appropriate high value-added information in a shorter timeframe than before. In the area of immuno-inflammation, in May of this year, we launched a new Simponi autoinjector formulation that improves patient safety and effectiveness and we are working hard to achieve its rapid market penetration. In the areas of diabetes and kidney disease, the CREDENCE study, which is the global evidence for Canaglu presented at international conferences, is being appropriately disseminated to healthcare professionals. We expect this preparatory marketing effort to facilitate sales of the HIF-PH inhibitor Vadadustat (MT-6548), which is scheduled for release in fiscal 2020.

We will also expand our points of contact in digital

marketing to ensure that these information provision activities are carried out. In order to seamlessly respond to diversifying needs, we will evolve to omnichannel, which merges digital and real world data (face-to-face information provision), and perform our industry-leading digital marketing. Further, by increasing the expertise of each MR, we will further boost our MR activities. This will be done in two ways, by accelerating consulting sales, which recommend the optimal treatment taking into account the disease's progression, and solution sales, which meet the needs of each region through the creation of regional networks such as medical facilities and nursing homes.

1. MCI Multimedia Whitepaper 2016 Winter Edition, 2018 Summer Edition.
2. IQVIA Data
3. Macromill CareNet fiscal 2018 Survey.

Medium- to long-term perspective

The greatest mission of this division from a medium- to long-term perspective is to develop growth and revenue strategies for sustainable growth.

With regard to our growth strategy, we will further increase our presence in priority areas in anticipation of the development pipeline.

Our revenue strategy will be to help secure funds for growth investments by promoting reforms to achieve an optimal organizational structure and advancing operational productivity reforms that actively utilize robotic process automation (RPA) to reform working styles and strengthen competitiveness.

Message to shareholders and investors

The business environment has changed dramatically in recent years and risks related to sales activities include drastic reform of the drug price system, promotion of generic drug and biosimilar use, and stricter regulations on visits and sales promotions to medical institutions. To deal with this sudden change, we need to create an organization in which employees have a clear awareness of goals and can quickly take on the necessary challenges. I also believe that creating this organizational culture is an important function. We want to continue to contribute to the health of as many patients as possible and to be a company trusted by society by promoting "the appropriate use of products," a material issue, strengthening our presence in priority areas, one of our strengths, and promoting information provision activities that meet market needs.

Mio Sogo
Product Marketing Department, Sales & Marketing Division Pediatrics West Japan Promotion Group Team Leader

Creating a system that provides up-to-date information that matches the needs of pediatricians

Since joining the Company, I have been involved in information provision activities as an MR. After that, I was assigned to a corporate division where I examined sales policies for vaccines and created sales promotion materials. Leveraging this experience, I'm now affiliated with an MR Group specializing in pediatrics that was established in October 2018. In addition to visiting pediatricians, as a leader of a team with six members including myself, I also support these members.

Our mission is to establish an overwhelming presence in the pediatrics field by gaining the trust of not only pediatricians, but also healthcare professionals and patients. In the pediatrics field, the latest information is most important, so it is necessary to constantly raise one's expertise. Various efforts are made when providing information, so we constantly work with feelings of tension, responsibility, and good faith.

Many female employees balance work with childcare, and working style reforms are also an important mission of our team leaders. In addition to existing sales styles, we are actively pursuing efforts to establish efficient and effective approaches. One of these was the introduction of ZEUS, an email system that sends information to doctors. This system enables information to be customized to suit each pediatrician that's in charge and provide more needed information. We are also taking steps to streamline communication by leveraging IT tools to hold meetings with team members working remotely in their respective areas of responsibility.

Supporting the health of children is also about creating Japan's future. Moreover, the vaccine business that we are rolling out in the field of pediatrics contributes to society by controlling medical costs from the standpoint of disease prevention, and I am proud and satisfied to be able to play a part in this socially significant business.