

# Mitsubishi Tanabe Pharma Corporation Medium-Term Management Plan 21-25

## Minutes of Investor Meeting (Presentation + Q&As)

March 3, 2021

Held as an online meeting

### Cautionary Statement

The statements contained in this documents are based on a number of assumptions and beliefs in light of the information currently available to the management of the company and are subject to significant risks and uncertainties.

The documents contain information about pharmaceuticals, including products under development, but is not intended for advertising or medical advice.

Attendees : Mitsubishi Tanabe Pharma Corporation  
President & Representative Director Hiroaki Ueno  
Representative Director, Managing Executive Officer Eizo Tabaru

## **Presentation**

### **President Ueno**

Hello everyone. I'm Hiroaki Ueno, the President of Mitsubishi Tanabe Pharma Corporation (MTPC). The business briefing session of Mitsubishi Chemical Holdings Corporation (MCHC) was held on the 25th of last month. Today, I would like to introduce the new Medium-Term Management Plan of our company, which is responsible for the healthcare field of MCHC. This session would have been held in a face-to-face meeting to allow me to directly communicate with all participants. However, due to the COVID-19 pandemic, we determined to have an online meeting.

### **P.3 Agenda**

Prior to the introduction of our new Medium-Term Management Plan, I will explain our new MISSION as well as VISION 30, which sets forth our business goals for 2030.

### **P.4 In preparation for the Medium-Term Management Plan 2021–2025**

The MTPC Group has decided to take a new step by changing its corporate philosophy and vision to its MISSION and VISION 30. In formulating the new Medium-Term Management Plan, at first, we considered the significance of our existence in the society of the future, and then reviewed issues including our achievements, future healthcare, and where we should plot our direction. Our company was established in 2007 by the merger of Tanabe Seiyaku Co., Ltd., with Mitsubishi Pharma Corporation. With the corporate philosophy of contributing to the healthier lives of people around the world through the creation of pharmaceuticals, we have been striving to become a global research-driven pharmaceutical company. With the launch of extremely well-received products such as Imusera and Canaglu, and with the release of Radicut in 2017, we achieved the long-sought goal of building our own sales base in the United States. We believe that this achievement allowed us to achieve our original vision. Then, when we imagined the future of healthcare and considered our value that we can provide for society and the significance of our existence. We determined that we need a new mission and vision.

### **P.5 Thoughts for the new MISSION**

Our intent for the new MISSION is represented by what we have achieved in our history of more than 300 years and by the significance of our existence in the society of the future. As one of the oldest pharmaceutical companies in the world, we have provided many unprecedented treatment options. Our history involves not only eliminating incurability, but also offering treatment options. The corporate DNA inherited by us is that we have persistently challenged, without giving up, to provide pharmaceuticals for

diseases without any effective medicine in the world, and that we have provided an answer at every opportunity. For patients, their families, and healthcare professionals, permanent cures and increasing treatment options mean freedom from the tyranny of the disease, and hope. Through the creation of pharmaceuticals, we have been continuously creating hopeful options. As the evolution of technology expands the possibilities, an era will come in which hope for those who face illness is not limited to conventional medicines. No matter how the environment changes, we will continuously create hopeful options. We have reaffirmed that this is the significance of our existence.

#### **P.6 New MISSION**

On April 1st 2021, we will change our corporate philosophy to our MISSION, which is dedicated to "Creating hope for all people facing illness." The new MISSION shows what the MTPC Group should do in society. We pledge that we will conduct our business activities in order to achieve this MISSION.

#### **P.7 What healthcare requires**

I would like to explain VISION 30. Regarding the Medium-Term Management Plan 2021–2025, we looked to the future of 2030 and then formulated the plan by backcasting the environmental awareness surrounding pharmaceutical companies. Although it is difficult to foresee the future of the rapidly changing pharmaceutical industry, we forecasted the environment in 2030 from these five perspectives. As a result, we understand future healthcare as follows: "The medical field will expand from hospitals to homes, and the degree of satisfaction of patients and their families will be emphasized. Total care integrated into daily life will be required." Looking ahead to this future, VISION 30 shows the corporate image in 2030 which reflects what should be done to fulfill the MISSION.

#### **P.8 VISION 30 and the value provided**

The goal of our VISION 30 is: "Be a healthcare company that delivers optimal therapy to each individual." We provide therapeutic agents and wide-ranging solutions designed with the patient and their family in mind. Based on that thinking, we formulated our five-year Medium-Term Management Plan.

#### **P.9 MISSION and VISION 30 for realizing KAITEKI**

We formulated MISSION and VISION 30 based on ideals that are also applied to KAITEKI, which is the concept of MCHC working for a sustainable society and earth. Achieving MISSION and VISION 30 in the society of the future will lead to the achievement of KAITEKI.

#### **P.10 Agenda**

I would like to explain the Medium-Term Management Plan 2021–2025. We will work on precision medicine and around the pill solutions as growth strategies to achieve VISION 30, which is our goal for 2030.

#### **P.11 Solutions that deliver new value**

In precision medicines, we provide medicines with high treatment satisfaction for the optimal patient groups, and develop around the pill solutions based on therapeutic drugs to respond to patients' problems. By taking these measures, we collect and analyze healthcare data so as to improve the value of medicines and solutions. We will achieve VISION 30 through the provision of these three values.

#### **P.12 Milestones to achieve VISION 30**

We have set milestones to achieve VISION 30. By 2025 of the new Medium-Term Management Plan, we will realize precision medicine and around the pill solutions for patients with unmet medical needs. We aim to achieve the prevention of sickness and of aggravation with technology as well as data by 2030, so as to contribute to the extension of healthy life expectancy of each person.

#### **P.13 Definition of precision medicine and social significance**

We have defined precision medicine as "providing the appropriate medical care to the appropriate patients at the appropriate timing." For diseases with diverse pathologies or symptoms, patients had to take several types of medicines to achieve treatment that suits them. Therefore, it required a significant medical expense to achieve satisfactory treatment outcomes. As a result, better medical efficiency was required. On the other hand, for precision medicine, patient strata of high benefit are identified beforehand to administer the appropriate medicines to the most appropriate patient group. Patients can receive the treatment best suited for them from the beginning, which will lead to more efficient medical resources.

#### **P.14 Fulfillment of precision medicine**

As for precision medicine, I would like to explain our specific efforts with Dersimelagon (MT-7117). Clinical trials of this drug are being studied in erythropoietic protoporphyria (EPP) and systemic sclerosis. EPP is a disease in which the skin aches when it is exposed to sunlight. The drug, which is a melanocortin 1 receptor agonist, increases melanin concentration. This enhances the barrier effect of the skin against ultraviolet rays. Thanks to the effect, patients can stay longer under the sunlight. As a result, the drug contributes to improving patients' QOL. As an initiative for precision medicine, we are proceeding with clinical trials that will enable an appropriate dose to be selected for each patient based on stratified analysis using biomarkers such as protoporphyrin concentration. On the other hand, for systemic sclerosis, therapeutic effect is expected from anti-inflammatory and anti-fibrotic effects through melanocortin 1 receptor. During Phase 2 clinical trials, we are planning to identify strata with high response to the drug by using blood or skin biomarkers such as genetic analysis. Starting with these measures, we will achieve our own precision medicine.

#### **P.15 New challenges to achieve precision medicine**

To create precision medicine, we need to further reform our drug discovery processes and increase open innovation. To tackle these new challenges, we will carry out two reforms. One is to quickly identify

the disease causative gene by collecting and analyzing genomes and genes. The other is to fulfill phenotypic drug discovery by collecting and analyzing clinical specimens and patient data. In the future, we will actively utilize open innovation. We will strive to promote the project while identifying target diseases from the initial stage of research.

#### **P.16 Building around the pill solutions and social significance**

I would like to explain initiatives for around the pill solutions, using amyotrophic lateral sclerosis (ALS) as an example. We believe that the starting point of the solutions will continue to be medicines. For ALS, we are considering initiatives that start with Radicava and MT-1186, an oral medicine of Radicava which is currently in Phase 3. We provide two initial solutions: Early diagnosis support and treatment support. To inhibit the progress of the disease through early diagnosis, we are working on the development of the diagnosis support solution. Please note that the progress of the ALS conditions makes continuous treatment difficult. We aim to reduce treatment burden on patients by providing the oral treatment support solution that allows them not to visit hospitals or medical institutions for treatments. By implementing these solutions, we would like to contribute to improving the quality of life of patients and their families. We believe that our contribution is the social significance of around the pill solutions.

#### **P.17 New challenges for around the pill solutions**

By establishing new customer contact points that are derived from around the pill solutions, we will collect and analyze healthcare data and expand the three opportunities shown on the slide. We will expand therapeutic opportunities by supporting early diagnosis based on data. We will use healthcare data to increase collaboration opportunities for new products and services. And we will extract new patient strata with differences in symptoms, etc., from collected data to expand opportunities for creating research and development themes for precision medicine.

#### **P.18 Strategic outline for fulfilling VISION 30**

For a specific disease, quickly identify a patient group, and then use precision medicine. Supposing that the patient group is Disease Group A, we will expand around the pill solutions from the Group. Utilizing the technologies and expertise obtained from Group A, we will expand drug discovery to other Disease Group B, C, D. As a result, for specific diseases, we will expand the scope of coverage from prevention to prognosis in some disease groups and will earn comments such as, "For this disease, we can rely on MTPC." The essence of our growth strategy is to develop business by using not only our products and services, but also alliances with other companies.

#### **P.19 Agenda**

I would like to explain basic strategies for the Medium-Term Management Plan 2021–2025.

#### **P.20 Achievement & challenge in medium-term management plan 16–20**

## **four strategic priorities**

I would like to explain the Medium-Term Management Plan 2016–2020, which is in its final year. In the current Medium-Term Management Plan, we have established a sales foundation in the United States, which has been our objective since our establishment. However, numerical targets became difficult to reach due to development plan changes and delays for growth-driver products. In the current Medium-Term Management Plan, we have been working on four strategic priorities. As for Maximizing Pipeline Value, we advanced 10 drug candidates to late-stage development. However, we failed to launch in-house products created after the establishment of MTPC. In Accelerating U.S. Business Development, we established a sales foundation in the United States by launching Radicava in the U.S. market in 2017. Under Strengthening IKUYAKU and Marketing, we achieved domestic sales of 300 billion yen and raised the sales ratio of new drugs and priority products to 80%. However, our issue is to maintain domestic operating profit margins despite the influence of the business environment, such as NHI price revision. And regarding Reforming Operational Productivity, we reduced costs by 35.5 billion yen. In the future, we will work on improving productivity through genuine workstyle reforms.

### **P.21 Medium-term management plan 21–25 basic strategies**

Positioning these five years as the transformation period toward VISION 30, we will use it to lay the foundation for growth strategies. In research and development, we will create precision medicine focused on treatments of the central nervous system and immuno-inflammation. We will focus on a total of three areas including these two areas and the vaccines area. As for business development, we will strengthen business in the United States and Japan, and develop around the pill solutions to create new customer contact points. Regarding the management base, we will create a management foundation and optimize the allocation of management resources to achieve VISION 30.

### **P.22 Major development pipeline list**

This is the list of the major development pipelines. The list mainly shows Phase 2 and the subsequent projects in the areas of the central nervous system, immuno-inflammation, and vaccines. As products targeted for the global market, we will launch MT-1186 of Radicava oral suspension, ND0612, MT-7117, and MT-2766,. In Japan, we will launch six types of medicines, including the products targeted for the global market during the period of the new Medium-Term Management Plan.

### **P.23 Central nervous system area strategies**

This slide shows strategies for the central nervous system area, which is one of our core areas of research. With ALS, which has a lot of drug discovery information cultivated by Radicava, we will use it as an entry point to quickly identify the genes of intractable neurological diseases, which share causative genes or pathophysiology, and take on the challenge of creating new modalities. Our research centers in Yokohama and Shonan iPark will be responsible for drug discovery from identified genes. In addition, Neuro Discovery Lab, which was announced in today's press release, will be established in Boston and

will verify and research target genes. By using these two approaches, we will find a drug discovery target, select the optimal modality for that target, and proceed with drug discovery research. Currently, we are proceeding with several projects in the fields of gene therapeutic agents and nucleic acid medicines. We will start clinical trials for the projects during the Medium-Term Management Plan period to advance their stages. Furthermore, in order to contribute to improving the quality of life of Parkinson's disease patients, we aim to launch ND0612 in 2024.

#### **P.24 Immuno-inflammation area strategies**

The immuno-inflammation area is characterized by diseases like systemic sclerosis and systemic lupus erythematosus which cause various symptoms and for which there are few effective drugs. For such autoimmune diseases, we aim to provide medicines for the optimum patient group by discovering phenotype-based drugs, which are derived from the phenotypes of the patient's symptoms, instead of adopting the conventional direct approach to drug discovery targets. In this effort, we will use bioinformatics technologies to analyze phenotypes of clinical specimens and patient data that are collected from joint research with Keio University's Research Park. Based on the analyzed phenotypes, our research centers are working on developing drugs. We are proceeding with multiple research projects on small molecules and antibodies. We will start these clinical trials during the Medium-Term Management Plan, aiming to advance the stages.

#### **P.25 Digital transformation (DX) of research and development**

Next, I will explain the digital transformation of research and development. In the research stage, we will further promote the use of digital technology to analyze clinical samples. In the central nervous system area, we will analyze gene networks to comprehensively search for association with known disease genes, accelerating the identification of new disease-causing genes. In the immuno-inflammation area, we will perform simultaneous multilevel analysis of various factors including clinical data, cellular phenotypes, genes, and protein expression to implement targeted phenotypic screening. For the functional evaluation of clinical development, we will adopt digital biomarkers to establish new evaluation methods. By using sensing technology for capturing movements, we will enable functional evaluations for intractable neurological diseases. We will elevate around the pill solutions to solutions that will capture the ALS symptom of shivering, and support early diagnosis.

#### **P.26 Vaccine area strategies**

Next, I would like to explain vaccine strategies for contributing to preventive medicine. Our vaccine business consists of two pillars. The first pillar is to launch plant-derived VLP vaccines developed by Medicago Inc. The second pillar is to collaborate with the BIKEN Group. The collaboration aims to contribute to the prevention of domestic infectious diseases. As for VLP vaccines, MT-2766 for COVID-19 is undergoing phase 2/3 clinical trial in North America. The vaccine is combined with an adjuvant developed by GlaxoSmithKline plc., and is expected to enhance immune responses and improve the

acquisition of immunity. We have already signed a subsidy and supply contract with the Government of Canada, aiming to launch the vaccine in 2021. In Japan, we will endeavor to launch MT-2355, which is a combined vaccine of five types, and to raise awareness of inoculation of varicella vaccine. BIKEN Co., Ltd., which was established as a joint venture with the BIKEN Group, will work to improve productivity and further strengthen its foundation.

#### **P.27 Approach to with/post COVID-19**

To overcome COVID-19 and contribute to preparation for a future pandemic, we are applying two measures: vaccine and treatment. As for the vaccine, we will contribute to the prevention of COVID-19 by development of MT-2766 by Medicago Inc. On the other hand, in terms of treatment, we have started COVID-19 collaborative research with Keio University's School of Medicine on neutralizing antibodies that can be applied to the treatment of COVID-19. In addition, we will contribute to the prevention of aggravation and treatment by repositioning our immunology project.

#### **P.28 Business development strategies**

I would like to explain our business development strategies. We are mainly giving high priority on the US and Europe, Japan, China and Asia. We are positioning the United States and Europe as the growth drivers for our company in the future. We will steadily launch late-stage products to these markets to expand the scale of our business. To maintain the Japanese market, which is our home market and the source of our profits, we will deepen the current businesses foundations and broaden them to new business foundations. In China and Asia, we will introduce products launched in the United States and Japan to China and Asia to maximize the value of our global products.

#### **P.29 Business development strategies for the US and Europe**

For ALS, we will utilize a network with KOL, established through Radicava, and relationships with ALS communities as well as payers to maximize the value of MT-1186, reducing treatment burden on patients and Exservan, a Riluzole oral film, for which a contract was concluded in January this year. For these efforts, we will implement around the pill solutions, a combination of early diagnosis and medication support, to improve patient engagement and strengthen our business foundation. As for EPP, we will leverage know-how on rare diseases obtained through Radicava business and implement medical plans as well as around the pill solutions to maximize the value of Dersimelagon. As for Parkinson's disease, we will prepare to create a sales foundation to achieve the swift start-up of ND0612.

#### **P.30 Business development strategies for Japan**

To further our current operations, we will take the three measures shown on the slide. We will maximize the value of priority products and new products by focusing on medical activities and sales resources. We will advance strategic in-licensing and alliances centered on our strengths in medical departments. And we will improve customer engagement by using big data on sales. At the same time, we will work on



broadening to create new business foundations. Also, we will develop around the pill solutions to create new customer contacts, and will build a management platform for health care data. By taking these measures, we will strengthen our business foundation in four segments of the Japanese market, which are diabetes and kidney, immuno-inflammation, the central nervous system, and vaccine.

### **P.31 Business development strategies for China and Asia**

We aim to achieve a rapid penetration of the products launched in the United States or Japan and to maximize their value. At the same time, we will streamline our business to boost profitability and create strong business foundations. In China, we will build foundation for becoming a specialty pharmaceutical company in 2030. In South Korea, we will maximize product values by utilizing new strengths in the central nervous system area. In Taiwan, we will use our current strong presence to strengthen our business and expand our product lineup. In ASEAN, we will introduce products catered to each country's needs as well as their business stages and develop current products.

### **P.32 Three strategies for fulfilling VISION 30**

Regarding our management base, I will explain the three initiatives for fulfilling VISION 30, which are strategic investments, organization and human resources reform, and digital transformation.

### **P.33 Strategic investment**

We will invest on not only R&D, but also various fields by utilizing our strategic investment funds for three objectives. These are promoting strategic introduction and alliances to strengthen our business, discovering drugs and obtaining manufacturing technology for precision medicine, which is the essence of our growth strategy, and utilizing digital technology for around the pill solutions. By active investments, we will achieve our growth strategy for VISION 30.

### **P.34 Organization and HR reform**

We will promote expertise, diversity, and digitization to foster innovation. In order to train and secure specialized personnel, we will respect voluntary learning, support career formation, and expand career opportunities. Furthermore, we will train and employ personnel who have diverse expertise and design thinking. In addition, we will further accelerate diversity measures to build a highly diverse workforce. The pillars of these measures are to recruit people for the most appropriate occupations and positions, regardless of age, gender, or nationality, and to establish a system that allows employees to have diverse values and work styles. In addition, we will promote digital transformation in our organization. It needs to develop digital specialists and raise the level of digital literacy. We will accelerate our digital transformation by executing an in-house program to develop three types of digital specialists and by reviewing our business processes.

### **P.35 Real workstyle reform that creates new value**

From the perspective of diversity, I will explain the genuine workstyle reforms that create new value for our company. We are considering taking three measures for the new value. The first measure is to apply digital technology to improve work efficiency and increase the productivity of each employee. The second measure is remote working, which has become more common due to the COVID-19 pandemic. We will utilize work styles unbound by time and place and provide new opportunities for independent learning that will improve expertise and spur innovation. The third measure is to deepen values cherished by and shared in our company while we accept diverse values and changing working styles. For this measure, we will instill our MISSION and VISION 30.

#### **P.36 Digital transformation**

I would like to outline our measures for digital transformation. We will further promote the establishment of three digital infrastructures and aim to create new pharmaceuticals with the use of digital technology. By applying around the pill solutions, we will create new customer contacts and implement R&D and services improvements by utilization of data. As for our value chain, we will fully utilize the effect of digital technology to improve productivity.

#### **P.37 Synergy as Mitsubishi Chemical Holdings Group**

After becoming an independent subsidiary of the MCHC Group, we established a committee to explore ways to generate synergies. In order to produce synergistic effects in the Group, the committee members discuss three themes: Corporate synergy, business synergy, and digital transformation. Several projects are already in progress. The entire Group will work together to create new synergies.

#### **P.38 Materiality that contributes to SDGs**

I would like to explain our managerial goals. These are material issues that contribute to the SDGs. We have made partial changes or additions in material issues formulated in 2018 and will work on eight material issues. We have newly reviewed access to healthcare, stakeholder engagement, and environment-friendly business. Each of the eight material issues must be addressed. Strongly confronting these issues will lead to the achievement of our MISSION, VISION 30, and finally the SDGs.

#### **P.39 Management policy**

I would like to explain our managerial policy. In the Medium-Term Management Plan 2021–2025, as we look toward making great progress in 2030, we will focus our growth strategies on precision medicine and around the pill solutions. By building a competitive advantage in fields of specific diseases, we will expand our partnering opportunities and shift to a policy that aims to grow beyond our own products and services. To achieve growth strategies, we will invest on not only R&D, but also various fields including drug discovery platforms and digital technologies. We will establish a drug discovery approach based on disease causes and phenotypes, and at the same time, we will develop solutions based on therapeutic drugs to build the basis of VISION 30.

#### **P.40 Fulfilling our MISSION to provide new value**

I would like to summarize the Medium-Term Management Plan 2021–2025. I have so far explained our MISSION, VISION 30, and the new value that will be provided as we transform in the future. We will utilize the DNA which we have developed, and the drug discovery capabilities as well as creativity with which we have created “Options” with unprecedented hope to develop precision medicine and around the pill solutions so as to “Be a healthcare company that delivers optimal therapy to each individual.” as set forth in VISION 30. We will work on these tasks for creating hope for all facing illness. As the new MTPC Group, we will do our utmost to achieve the goals of the Medium-Term Management Plan 2021–2025.

#### **Q&A**

##### **Questioner 1**

Q1

Please tell me about the concept of precision medicine. Tell me the difference between precision medicine and conventional tailor-made medical care. Since precision medicine involves grouping, your thinking is that precision medicine does not cause segregation? Also, you said your company will collaborate with partners to expand drug discoveries to disease groups surrounding the patient group which is the original target of precision medicine. Please tell me how you will compensate for the missing pieces.

A1 (President Ueno)

The term “precision medicine” is widely used. We have defined it as “providing the appropriate medical care to the appropriate patients at the appropriate timing.” We will create effective medicines for each patient group and administer them at the appropriate timing. The important points are to stratify patients and identify each patient group. For these points, it is necessary to collaborate with medical-care-related organizations, mainly academic organizations. As for delivering medicines, we need to consider medication methods, medication timing, and a long period of medication. These factors cause us to collaborate with other companies with various technologies. We would like to perform many clinical trials, mainly for Radicava, which are now in progress, as well as for the subsequent MT-1186. I think that racial differences affect certain diseases. When utilizing genetic information, we will surely face ethical issues across countries. By carefully considering such issues, we need to determine target diseases and approaches to the diseases.

Q2

ND0612 was supposed to be launched in 2018, but the launch was delayed. However, your company neither reported an impairment loss immediately nor in May last year. It was finally reported six months

later. Please tell me what kind of policy your company will adopt in the future, regarding risk management. Also, please tell me if your company thinks that the risk management of ND0612 was handled properly.

A2 (President Ueno)

ND0612 was affected by COVID-19, in addition to some challenges with the drug by itself. While monitoring the infection status of COVID-19, we are expanding the area of clinical tests. We are cooperating with NeuroDerm Ltd. to strictly manage the progress of the clinical trials. We are striving to overcome the issues we faced in the past.

A2 (Managing Executive Officer Tabaru)

The clinical tests are not suddenly delayed in March 2020, but instead, we gradually came to understand the situation. As for the timing with booking the impairment loss and how much of a gap was created in our business plan, we are complying with the accounting rules. We needed time to make assumptions in order to solidify the figures. After consulting with certified public accountants, we booked the impairment loss in September 2020. During the review of the 2018 mid-term plan, we changed the target year to 2021 due to a delay in the development of the medicine. However, , we determined that we did not have to immediately book impairment loss as a valuation.

Q3

ALS is a disease for which there is no cure. Therefore, I think that it is effective to expand the surrounding area with penetration. Regarding niche serious diseases, please tell me if your main idea is to expand target niche intractable disease groups and provide solutions to make it areas or is to aim at even large ones. Tell me if your company will implement a niche strategy or not?

A3 (President Ueno)

Currently, it is a niche strategy. If the volume of stratified patients increases to a determined level, we will consider implementing the strategy on a wider scale. We will identify patients and consider what types of services or solutions can be provided to them.

## **Questioner 2**

Q1

Regarding MT-2766, a COVID-19 vaccine, I remember that your company has set a goal of over 100 billion yen of vaccine area. Your company predicts that one billion units of your vaccine will be sold. The prediction is based on 80 million doses capacity under an endemic. Currently, three pharmaceutical companies have already launched their vaccines, and two others are about to launch theirs. Under these circumstances, does your company predict the capacity of the global COVID-19 vaccine market? Tell me how your company can contribute to the prevention of COVID-19? Also, if you sell one billion units of vaccine, the total sales will exceed 100 billion yen. Please tell me the details.

A1 (Managing Executive Officer Tabaru)

If you multiply the capacity by the expected price, what you mentioned may be true. However, at this point, we are skeptical about the prediction that the COVID-19 pandemic will end within a year or so and become an endemic. The reality is that we have not yet made highly accurate forecasts of factors such as our competitors' business plans, assumptions, and our capacity, etc. Under these circumstances, our target in the vaccine business is 100 billion yen in 2025 in which we have been collaborating with the BIKEN Group in Japan in addition to Medicago's developments of a COVID-19 vaccine. We want to achieve sales of about 100 billion yen in 2025 from both.

Q2

The development pipeline does not contain MT-8554. It seems that Phase 2 is over and you have been preparing for Phase 3 for a long time. Please tell me what is going on.

A2 (President Ueno)

In the United States, MT-8554 was applied for hot flashes as well as VMS (post-menopause with vasomotor symptoms), and finally Phase 2 was completed. We are determining what to do in the future. Our focus is on the central nervous system and autoimmune diseases, and we are considering measures, including partnering, for VMS, which belongs to the gynecological field. There is no doubt that MT-8554 is an important pipeline. How to make it into a business is an issue to be discussed in the future.

Q3

Please tell me if your company thinks that profits will remain almost flat during the next five years.

A3 (Managing Executive Officer Tabaru)

APTSIS25 announced by MCHC is a medium-term plan consisting of two years and additional three years. The explanation is that we cannot exactly predict when the COVID-19 pandemic will be over. We have formulated the Medium-Term Management Plan 2021–2025, but we have judged that the figures have not yet reached a level requiring explanation.

### **Questioner 3**

Q1

How will your company connect around the pill solutions to profits? Will you use the solutions to maximize profit opportunities for medicines? Will you produce revenue solely from around the pill solutions?

A1 (President Ueno)

At this point, we want to expand medication opportunities to increase pharmaceutical sales. If,

depending on cases, around the pill solutions by themselves can be a business, we will think actively. Currently, you may understand that our company uses the solutions to maximize profit opportunities for medicines.

Q2

What has changed since MCHC acquired 100% ownership of your company? When approving of the TOB, your company explained that you will be able to invest on necessary research and development without being overly bound by periodic profit or loss. However, the R&D expenses for this term have decreased compared to those before the acquisition. Will the acquisition boost R&D expenses and the increase of your earning power in the future? Also, please tell me if there are any initiatives in this Medium-Term Management Plan that were made possible as a result of the acquisition.

A2 (Managing Executive Officer Tabaru)

We cannot fully invest in R&D due to the influence of COVID-19. Without such influence, we could have performed planned some activities. Currently, we are drawing up the budget for FY2021. Since our core operating income is not so high, we predicted that R&D expenses would be around 80 billion yen. However, since we are conducting four Phase 3 clinical trials, the R&D expenses will rise to 80 to 90 billion yen. We will draw up the budget while consulting with MCHC.

A2 (President Ueno)

By becoming a wholly owned subsidiary of MCHC, we expect to create synergies among business corporations, and MCHC. Since April last year, a committee has been formed to discuss the creation of three synergies themes. For business them, six themes projects have been approved, and we are working on them. For example, value is being created by combining the materials of MCC with the pharmaceuticals of MTPC, and the basic technologies required by both companies are being established through cooperation.

#### **Questioner 4**

Q1

In November 2019, when your company announced that you would become a wholly owned subsidiary of MCHC, you said that your company would be able to explain synergies for the Medium-Term Management Plan 2021–2025. However, your company has not formulated a policy up until now. Please explain the delay, as well as what has been formulated to some extent, such as cost reduction measures. Also, please tell me about the specific details of the six themes.

A1 (President Ueno)

We already have basic ideas. For example, unified operation of corporate functions such as personnel, legal affairs, accounting, and finance will increase in efficiency and be improved. Specifically, our legal

department is integrated with that of MCHC and executing its duties. Business synergies are mainly related to R&D. Therefore, we cannot discuss them in detail at this time. As for profitability, business synergies receive the highest expectation. We will be able to explain them when business synergies related to the R&D of pharmaceuticals become more concrete. We are not in a situation where we can talk about numerical values at this time. Two years from now, during Step 2, I will explain business synergies to the extent possible at that time. Please be aware that it will take some time for business synergies to produce results. Life Science Institute, Inc., is conducting clinical trials for indications such as cerebral infarction by using Multi-lineage differentiating Stress Enduring cell (Muse cells). MTPC is providing support for the clinical trials so that they will proceed smoothly. If something needs to be explained, Life Science Institute, Inc., will provide an explanation.

Q2

Regarding MT-2766, please tell us about the superiority of your company's VLP vaccine, such as production speed and storage temperature, compared to existing vaccines. Also, is it effective against mutant strains?

A2 (Managing Executive Officer Tabaru)

We can quickly produce VLP. Since the storage temperature is 2–8°C, VLP is superior in terms of distribution and storage. Other companies have already launched their vaccines to the market. However, given the number of the people who need vaccines, we have decided that we should deliver our VLP vaccine to the market as soon as possible. Medicago Inc. is studying mutant strains. However, it has not yet reached the first stage of clinical trials.

## **Questioner 5**

Q1

Uncertainty may be involved in the COVID-19 vaccine. However, please tell me if your company cannot predict its quantity or unit price. Pfizer Inc. says that the unit price of its vaccine will actually increase in an endemic situation. Please tell me your company's ideas about the conditions surrounding your COVID-19 vaccine. How does your company see the plan for supplying your vaccine in Japan?

A1 (Managing Executive Officer Tabaru)

At this time, we cannot disclose the vaccine price for the pandemic, due to a contract. It's not as if there is a market. We cannot unilaterally calculate the vaccine price. We have already signed a supply contract with the Government of Canada. The contract would indicate a rough standard. There is a market for seasonal influenza vaccines. Therefore, at this point, we are referring to them and discussing among ourselves. Regarding the introduction of our vaccine to Japan, we are currently focusing on phase 2/3 clinical trials in Canada and the United States. When it comes to introduce our vaccine to Japan, we need to consult with the authorities. At this point, we are at the consulting stage, and we cannot explain our

future schedule. I refrain from making a comment on whether or not an endemic will increase vaccine unit prices or on other companies' predictions.

Q2

Radicava was approved in China in 2019. Please tell me what kind of business plan you have for this. There are risks in China. For example, generic drugs may be produced soon, and pharmaceutical prices may suddenly drop due to centralized purchasing. Please tell me what kind of strategy your company have in mind.

A2 (President Ueno)

Basically, we will have our own sales channel. We have obtained approval, but we have to overcome some issues before launching the medicine to the market. We are uncertain about the plan which we will have according to circumstances after overcoming the issues. There are many things to work on regarding these issues.

#### **Questioner 6**

Q1

P. 13 shows that your company will apply precision medicine to cures. Are you going to apply precision medicine to patients enrolled in clinical trials?

A1 (President Ueno)

Ideally, we believe that stratifying patients should start at the research stage. If that becomes possible, we will conduct clinical trials only on specific patients. We hope that the probability of successful clinical trials will be higher than ever.

Q2

As for precision medicine, is your company paying attention to pipelines other than MT-7117?

A2 (President Ueno)

We have some projects which are not specifically shown. They include developed medicines to which precision medicine can be applied, and medicines for which patients are stratified at the research stage. The proportion of such projects is expected to increase.

#### **Questioner 7**

Q1

As for digital transformation, you said that your company will develop in-house specialists. However, the number of specialists in the world who can connect business, mathematical analysis, data science and carry out design-oriented tasks is limited. What kind of policy to develop specialists and hire them



from outside is? Is your company providing such specialists with different types of salaries or treating them differently? Or is your company going to provide them with rewarding work, even though the way such specialists are to be treated is set forth in the framework of the personnel system? Or is your company going to change the personnel system itself?

A1 (President Ueno)

We are considering a personnel policy for recruiting not only digital specialists, but also employees who have the skills or experience that we need. As for the compensation system for recruiting such employees, we are considering recruiting employees whom we require, even when we need to go beyond the conventional way of thinking. Whether or not we will change the personnel system in the future is an issue for us. At this point, we believe that we can deal with the issue by applying the personnel system flexibly depending on necessity. We must also consider the risk that trained specialists may be hired away by other companies. Rewarding work is a great incentive for people. We will consider using it to recruit talented personnel.