

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

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Message from the President



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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 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.

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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.



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

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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 CO₂ 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.

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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

Masayuki Mitsuka

President & Representative Director