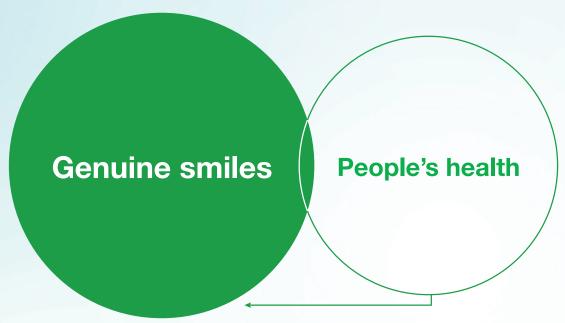




# **Vision**

# We contribute to people's health We are dedicated to people's genuine smiles



Supporting genuine smiles through everything that is contributing to health

Towa Group contributes to people's health by creating superior products and services.

Through our corporate activities, we aim to be a company that is valued and needed by patients, medical professionals, local communities, and others.





### **INDEX**



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[Editorial Policy] We issue Towa Pharmaceutical Integrated Report to communicate to shareholders, investors, and other stakeholders Towa Group's efforts to enhance our corporate value. This year's report presents our value creation story in the value creation process and the message from the President. It also explains our efforts to realize our vision through the 5th Mid-term Management Plan (2021–2023) PROACTIVE II formulated in May 2021. We strive to improve the content of the report to respond to various opinions and interests of our stakeholders. We look forward to your candid feedback.

[ Scope Covered ] Towa Group's consolidated accounts including some consolidated and non-consolidated figures in Japan.

[ Period Covered ] FY2020 (From April 1, 2020 to March 31, 2021)

\* The financial information is as of March 31, 2021. The report also covers some initiatives that were taken before April 1, 2020 or after March 31, 2021.

[ Guidelines for Reference ] International Integrated Reporting Framework issued by the International Integrated Reporting Council (IIRC) Guidance for Collaborative Value Creation issued by the Ministry of Economy Trade and Industry

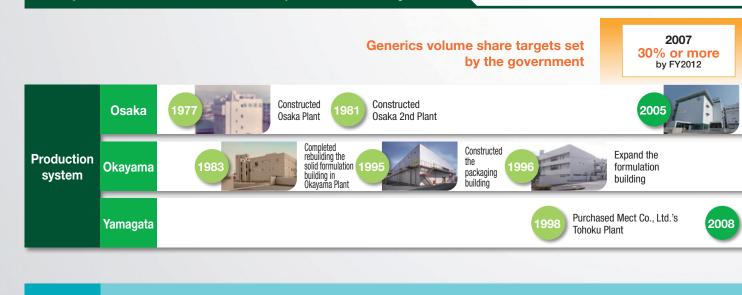
[Forward-looking Statements ] In this report, described statements other than historical facts are future forecasts based on forward-looking statements and plans. These future forecasts contain factors, such as risks and uncertainties, and actual results and performances may differ from the forward-looking statements.

# **Our History**

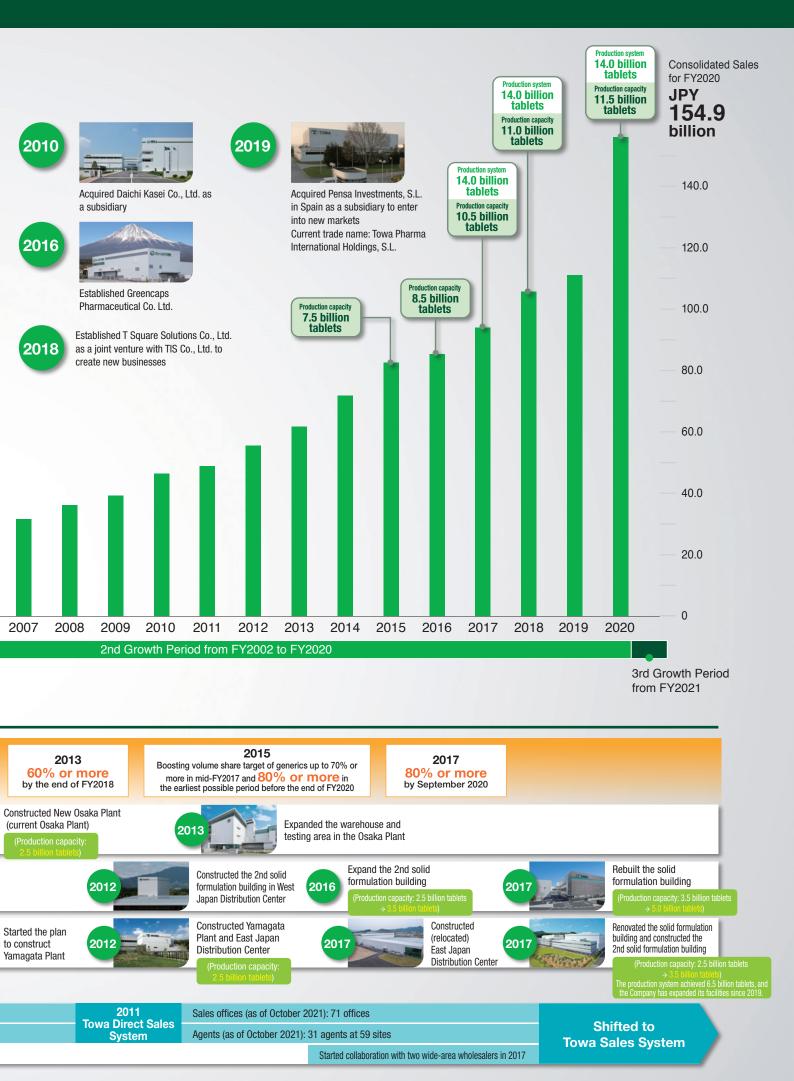
Since our establishment in 1951, we have strived to research, develop, manufacture, and sell generics for 70 years. While promoting stable supply, quality assurance, and information provision, we will continue to focus on research and development of ingenious pharmaceutical products that are "easier to take" and "easier to handle." At the same time, we work to construct a structure that can provide Towa Group's value-added products to patients around the world and to create new health-related businesses in response to the new medical system.

### **History of Towa** \*The years shown are fiscal years. 1951 Established 1996 2000 Launched value-added products Itsuro YOSHIDA was appointed President Acquired J-Dolph Co., Ltd. as and Representative Director 1957 Started selling OTC drugs 2003 a subsidiary 1997 Shifted to manufacturing and Established 1965 selling ethical drugs from OTC 2004 **RACTAB Technology** drugs Constructed new corporate headquarters 1998 Listed on the first section of 2004 the Tokyo Stock Exchange Constructed Osaka Research Center [Trends in Consolidated Sales] X 1951 1970 1980 1990 2000 2002 2003 2004 2005 2006 1st Growth Period from our establishment to FY2001

# History of initiatives based on measures to promote the use of generics



Sales system



# Social Issues Addressed by Towa Group

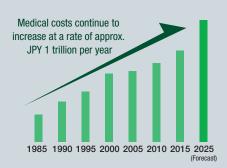
Japan's National Health Insurance System boasts the highest degree of fulfillment in the world. Every individual must save on medical costs to maintain this system. In this regard, choosing generics is an easy way for everyone to save the costs and one of the possible social contributions in our daily lives. We will address the social issues by creating related businesses that contribute to human health with generics business set as our core business.

# **Challenges**

# Swelling medical costs in Japan

# To maintain the National Health Insurance System in the future

In Japan, medical costs continue to increase at a rate of approximately JPY 1 trillion per year in the context of an aging population and sophisticated medical care. The Ministry of Health, Labour and Welfare estimates that the amount will exceed JPY 60 trillion in 2025. On the other hand, as the workforce supporting insurance premiums and taxes decreases, the prerequisites for system design are likely to collapse. If medical costs continue to swell as estimated, some undesirable events may happen: an increase in patients' burden of medical costs and the taxes, and a loss of access to medical care that we naturally have had up to now. Stemming the increase in medical costs is essential to keep the National Health Insurance System in the future.

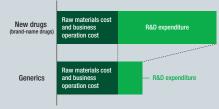


"Outline of National Medical Care Expenditure in 2015" released by the Ministry of Health, Labour and Welfare "Materials for the Medical Insurance Subcommittee, 76th Social Security Council"

# Choosing generics cuts medical costs

Choosing generics enables us to cut the burden of medical costs (drug costs). This will reduce both the burden of medical expenses on individuals and contributions by the Japanese government and health insurance associations. For instance, we can save approximately JPY 900.0 billion in the annual cost of drugs just by replacing as many drugs as possible with generics.

\*Our estimation as of July 2021



Comparison of drug prices (conceptual chart)

# Extension of healthy life expectancy and disease prevention

Extending the healthy life expectancy toward the era of the 100-year Life is a major issue in Japan facing a super-aging society. The healthy life expectancy is proposed by World Health Organization (WHO) in 2000. In the past, we had emphasized the average life expectancy of a child aged 0, indicating how many years he or she can live. However, the healthy life expectancy, a period of healthy living, has attracted attention in recent years. Preventing disease and staying healthy and active is key to prolonging the healthy life expectancy. Moreover, extending the healthy life expectancy is essential from the viewpoint of curbing medical costs.







# **Towa Group's Initiatives**

# Generics contribute to cutting medical costs

# Offering more than 750 products in our lineup

Desiring to be of service to as many patients as possible, we provide value-added generics through cumulative improvements by responding to and satisfying requests voiced by medical professionals. We offer more than 750 products in our lineup to cover various therapeutic areas. We manufacture our products with particular attention to active pharmaceutical ingredients (APIs) to deliver safe and secure generics, which is one of our unique features. Our mission is to deliver drugs that are not merely low-cost but "more easily taken and handled" to a large number of people.



# Ingenuity for products that can be more easily and safely taken by patients

Orally disintegrating (OD) tablets that can be taken without water



Masking technology used to reduce bitterness by coating tablets



Micro-granulation that reduces roughness perceived when taking medicines



Product name printing to make medicine identity easily discernable even after scoring



Smaller tablets with the same amounts of active ingredients







Efficacy labels and letters to make drugs more easily discernable





# Considering care of pre-symptomatic diseases and disease prevention as well as contribution in medical care

Based on our vision: "contribute to the health of people," we aim at contributing to medical care through generics business as well as through the care of pre-symptomatic diseases and disease prevention to extend the healthy life expectancy. In the care of pre-symptomatic diseases, we are developing a wide range of health-related initiatives, including developing new products and services, looking at returning conditions before the onset of illness to healthy conditions or preventing them from deteriorating. We have started initiatives for disease prevention, such as disease risk testing service business to keep good health.



# **Towa Group's Strength**

Generics are marketed later than new drugs (brand-name drugs); therefore, we can produce better products with the same efficacy, quality, and safety as the new drugs by utilizing the latest formulation technologies. We are engaged in various initiatives to provide easy-to-take, easy-to-handle, safe drugs, let alone quality and safety.



# **Developing and selecting the best API for manufacturing products**

We use APIs meeting our original strict quality standard among country-authorized APIs. We also actively research APIs and select the best APIs for creating products based on our accumulated know-how. Additionally, we have established a manufacturing method for the APIs in-house and a system to outsource the production of the APIs to Daichi Kasei Co., Ltd., a group API manufacturer, and a collaborative APIs manufacturer. We regularly inquire and confirm each manufacturer whether it manufactures the drugs in accordance with standards, laws, and regulations to enable the stable procurement of the API.

Related information See page



# Based on our technologies and experiences, developing products that can be more easily taken and handled

We have the lineup consisting of more than 750 products to cover various therapeutic areas. With the desire to serve as many patients as possible, we offer value-added generics by responding to voices and requests from medical professionals and reflecting them in our manufacturing process. Among them, we have been developed better dosage forms and tastes so that they can be easily taken by pediatric patients and the elderly, and enhanced visibility and stability against light, temperature, and humidity so that they can be easily handled at hospitals and pharmacies.

Related information See page 27.



# Working diligently to ensure reliable quality and safety

In order to be a trustworthy company, we comply with strict quality control standards stipulated by the government, from product R&D, manufacturing, marketing, and after-sale operations. We carry out company-wide quality control initiatives to establish the quality assurance system required for ethical medicines. Especially in manufacturing pharmaceutical products, we strive to ensure adequate quality and safety through our specific system, education and training, and other ways as well as to comply with the Good Manufacturing Practice (GMP) established by the government and other related laws and regulations.

Related information See page 42.

Fostering talented human resources



# Established production capacity with three plants to ensure stable supply at any time

By adopting a back-up system supported by three sites, we ensure that any production disruption at one plant can be compensated by efforts at the other plants. Furthermore, by dividing the physical distribution bases in East Japan and West Japan, we have established an efficient arrangement and a reliable back-up system even in a worst-case scenario. At present, all the three plants can produce a total of 11.5 billion tablets\* annually. We are expanding our production volume to 14.0 billion tablets by the end of FY 2022, aiming for further increasing demand. Furthermore, we plan to build 3rd solid formulation building in Yamagata Plant by the end of FY2023 and achieve the production capacity of 17.5 billion tablets after FY2024.

\*Production capacity of tablets and capsules

Related information See page 41.



# Active provision of relevant information to enable patients and medical professionals to feel comfortable while using ethical medicines

We have established a system that enables the prompt and appropriate provision of information on the proper use of our products and academic information to medical professionals, mainly through specially trained medical representatives (MR), to ensure that generics are used with reassurance. We also provide patients and their families with information to ensure their safe use of pharmaceuticals. In addition to providing information, we collect opinions from medical institutions and share feedback internally for creating better products.

Related information See page 40.





# Focusing on making job satisfaction and fostering talented human resources aiming for being a reliable company

We aim to be a more trusted and needed company as a comprehensive generics manufacturer. Under the belief that talented human resources are the foundation of a trusted company, we work to make job satisfaction, foster talented human resources, and strengthen our organization. The 5th Mid-term Business Plan 2021–2023 PROACTIVE II that will end in FY2023 sets out "Making Job Satisfaction and Fostering of Talented Human Resources" as one of the priority policies. While aiming for job satisfaction for each employee motivated by individual talent improvement and career enrichment, we seek to strengthen our system for encouraging employee growth.

Related information See page 43.



# Towa works diligently to ensure reliable quality and safety of generics.

In recent years, the generics industry saw various issues arising from quality and safety matters. Towa acknowledges these incidents as a situation that may undermine trust in all generic drugs. This section introduces our manufacturing control and quality control initiatives for pharmaceuticals.

# Compliance with the three principles of GMP

Pharmaceutical production is based on GMP\*, a standard laid down by the nation for manufacturing control and quality control of pharmaceutical products. GMP is composed of three principles: 1) minimizing human error, 2) preventing contamination and quality degradation of medical products, and 3) designing a system to assure high quality.

In order to have patients take generic drugs without feeling uneasy, Towa not only complies with relevant regulations including GMP ordinance, a standard for manufacturing control and quality control of pharmaceutical products, but also establishes its original system and education and trainings, among others, so that the employees can acquire proper understanding of the meaning of "minimizing human error," one of the GMP three principles. In this way, we strive to assure adequate quality and safety of generics.

To be specific, the procedures set out at all the three plants of Towa, located in Yamagata, Osaka, and Okayama, follow the three principles of GMP. Furthermore, employee trainings are carried out on a continuous basis to ensure high awareness among each and every employee as a pharmaceutical manufacturer and to encourage such a mindset in the daily work. In addition, we proactively adopted

international guidelines such as PIC/S GMP and ICH Guideline to manufacture appropriate goods under stricter rules and to create a system that is more capable of eliminating human errors.

Mock audit was carried out at Yamagata Plant by an external institution (former FDA investigator) to confirm conformity with the international standards. The plant was found to be compliant, and we are expanding the audit to other plants as well.

\*GMP: Good manufacturing practice. A standard for strict manufacturing control and quality control in pharmaceuticals production.

# Double checked by human and the management system adopted

Towa works to minimize human errors, one of the three principles of GMP, by introducing a manufacturing execution system (MES\*1) that supports the management and control of production process and gives directions to workers using computers, and also a laboratory information management system (LIMS\*2) that supervises and controls the management of quality testing of pharmaceuticals.

In parallel to these systems, the products are double checked by human to increase the elimination of human errors. As a generics manufacturer that produces a wide range of pharmaceutical drugs, we are making the detailed check system function at





each production process through thorough management using MES and LIMS systems in addition to performing human check.

- \*1 MES: Manufacturing execution system. A system to manage and control production process and give directions to and support workers.
- \*2 LIMS: Laboratory information management system. An integrated management system for testing where analysis results are directly entered into the system from analytical instrument via network.

# Education and training, and original qualification system

In addition to implementing systems such as MES and LIMS to minimize human errors in the manufacturing process and the quality testing, we prepared a manual that lists the details of the authorization document and specifies the pharmaceutical requirements behind those rules, for observation during production. We use this manual in education and training intended to instill the importance of adhering to the authorization document in manufacturing products.

Furthermore, in addition to the general education and training, we have introduced an original qualification system to recognize those with higher skills and knowledge in departments such as manufacturing, packages, testing, and quality assurance, as an "expert." Our system ensures that specialists in each field perform manufacturing control and quality control, in addition to promoting the development of employees who have high awareness in quality assurance.

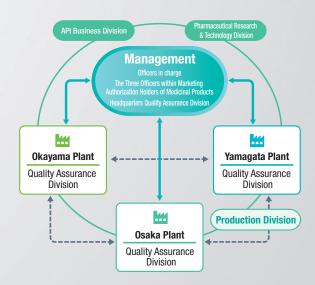
# Audit system backed by corporate wide involvement

Currently, Towa manufactures over 750 pharmaceutical products. In order to bring to the patients all these products after thorough quality control, we are conducting periodic audits in our plants as well as in outsourcing companies. The audits are led by the Headquarters Quality Assurance Division and are conducted by auditors certified based on GMP auditor system established by the Company.

Furthermore, we have organized a structure capable of providing technical advices and pointing out technical matters by including members who acquired qualification as a technical expert (in APIs, formulation, packaging, etc.) in the audit team. We will enhance the quality of GMP audit system through this approach, and going forward, strengthen the audit system by increasing the frequency of field audits. This will be done by implementing GMP auditor and technical expert education across the Company to raise the number of GMP auditors.

Headquarters and the three plants, meanwhile, are sharing information on quality issues and conducting case studies to work towards continuous improvement of quality control and to raise awareness on the matter. Furthermore, regular briefing sessions are attended by managements as well. By building a system where information is shared across people from those working in the field to top management without delay, we are striving to ensure adequate quality and safety of pharmaceuticals.

From personnel working in the field to top management, information is shared periodically to bring about prompt cooperation





# The EU/US Regional Headquarters leads the business development in **Europe and the United States.**

As a comprehensive generics manufacturer in Japan, Towa makes efforts to strengthen its quality assurance system, maintain a broad range of product lineup, and manufacture sophisticated products with No. 1 total product performance, while aiming to offer our value-added products to the overseas market. Based on our vision of "contribution to people's health," we are utilizing the sales network in several European countries and the United States as well as the production bases in Europe compliant to European and the United States standards to further expand our business not only in Japan but also globally.

# Established a bridgehead in developing business in the European and the U.S. markets

"Entry into new market" was laid out as one of our basic policy in the 4th Mid-term Business Plan 2018-2020 PROACTIVE. As part of our efforts to deliver our value-added products to overseas markets, we acquired Pensa Investments, S.L., a generics business company, from a Spanish pharmaceutical company, Esteve Group, in January 2020, making it a consolidated subsidiary. In July of the same year, the company changed its name to Towa Pharma International Holdings, S.L (hereinafter referred to as "Towa HD").

This series of actions effected Towa's advancement into the overseas market to proceed in full swing. Having Towa HD under our Group, we gained a market base for generics in Europe and the United States, knowledge in the manufacturing approval process in each country which had been our long-standing issue in advancing overseas, knowledge in business practice in different regions, and production facilities that have experience of exporting products to other countries and are in compliance with the standards of competent authorities in Europe and the United States such as European Medical Agency (EMA) and U.S. Food and Drug Administration (FDA). We expect that Towa HD will play the role as a bridgehead in offering Towa Quality products in a number of countries in the overseas market in the future.

# Aim to offer Towa's value-added products in Europe and the U.S. markets

The 5th Mid-term Business Plan 2021-2023 PROACTIVE II that began in FY2021 sets out "expanding and growing business in overseas market" as the second policy. We intend to increase the number of countries and regions in the overseas market where our products are sold while expanding the scale of our business through initiatives such as achieving sustainable business growth with Towa HD as a hub through new products launches in Europe and the United States, developing Towa Quality products meeting the needs of the overseas market, and exploration of market opportunities in new countries/regions.

As for Towa HD's business by region, it offers over 160 APIs mainly for gastrointestinal drugs in Europe. We are working to maintain and enhance our market competitiveness by launching new products utilizing the strength in ingenious formulation such as pellet formulation technology and implementing marketing strategy based on the data of each market. Additionally, we are expanding the B2B out-licensing of value-added products

developed in-house to a wide range of regions.

Meanwhile, over 70 APIs, mainly therapeutic drugs for high blood pressure and epilepsy, among other indications, are sold in the U.S. market. Going forward, we will develop the business by creating a strategic product portfolio based on our determination of which product has the least competitor, can anticipate market needs, and ensures profit, while reducing development risk by selecting business partners appropriately.

Furthermore, in order to offer our products that are acclaimed in Japan to overseas market in the future, we are exploring the potential needs for our value-added products in overseas countries and regions. We are also carrying out research activities aimed at advancement into new markets in addition to Japan, the United States, and Europe. We intend to establish a global business foundation centered around Towa HD to provide highquality, value-added generics to patients all around the world from the three poles, Japan, the United States, and Europe.

# Overview of Towa Pharma International Holdings, S.L. Group



# TOWA

# Towa Pharma International Holdings, S.L.



### EU/US Regional Headquarters located in six countries across Europe and the U.S. and provides products to over 20 countries worldwide

Currently, the company has business bases in five European nations in addition to one in the United States. It provides over 210\* APIs of generics in over 20 countries worldwide. The company controls Pensa Pharma, S.A., a generics sales company in Europe, Breckenridge Pharmaceutical, Inc., a pharmaceuticals sales company in the United States, and Towa Pharmaceutical Europe, S.L, a company that owns B2B business, plants, and a R&D base. It steadily operates the existing business while providing Towa's value-added products to European and the U.S. markets in addition to promoting further advancement into new markets.

Headquarters location: Catalonia, Spain Established: 2019

Business: EU/US regional headquarters Number of employees: Approximately 30 \* The figure includes no double counting between Europe and the United States.



# Breckenridge Pharmaceutical, Inc.



# **Generics business company in the United States**

Headquartered in Berlin, Connecticut, United States, Breckenridge Pharmaceutical, Inc. engages in generics business in the country. It analyzes the competitive environment and the needs in the fast-changing U.S. market, and builds and enhances strategic product portfolio.

Headquarters location: Connecticut, United States Established: 1983

Business: Generics business mainly in the United States Number of employees: Approximately 50 Business bases: One in the United States





# Towa Pharmaceutical Europe, S.L.



### Generics production base in Europe

Headquartered in Barcelona, Catalonia, Spain, Towa Pharmaceutical Europe, S.L. engages in manufacturing of generics including those marketed as pellets, capsules, tablets, and liquid formulations. The company also engages in the research and development of new products. It operated under the name Dose Innova, S.L. before changing it to the current name in June 2020. Since the company has production facilities meeting the European and the U.S. approval standards, it takes on an important role in realizing the policy of "developing Towa Quality products meeting the needs of overseas market."

Headquarters location: Catalonia, Spain Established: 2019

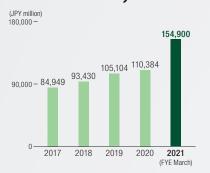
Business: Manufacturing of pharmaceuticals and a base for research and development Number of employees: Approximately 600 Building area: Approximately 35,000 m<sup>2</sup> Products manufactured: Pellets, capsules, tablets,

liquid formulations, and others

# **Financial Highlights**

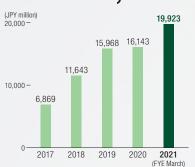
### **Net sales**

JPY 154,900 million



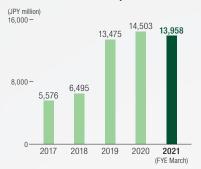
### Operating profit

JPY 19,923 million



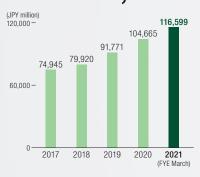
# Profit attributable to owners of parent

JPY 13,958 million



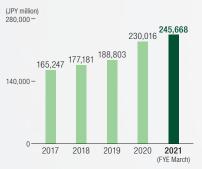
### **Net assets**

JPY 116,599 million



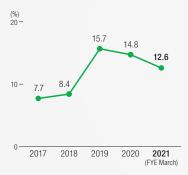
# **Total assets**

JPY 245,668 million



# ROE

12.6%



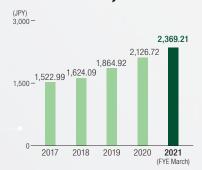
### Earnings per share

JPY 283.62



### Net assets per share

JPY 2,369.21



### Dividend payout ratio

15.5%

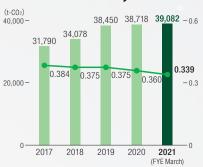


Note: The Company conducted a 3-for-1 stock split of common shares effective April 1, 2019. We calculated net income per share and net assets per share assuming that the said stock split had been conducted at the beginning of the fiscal year ended March 31, 2017.

# **Non-Financial Highlights**

### CO<sub>2</sub> emissions

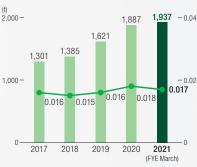
39,082<sub>t-C02</sub>



- \* Three Towa plants
- \* Per sales of JPY 1 million (non-consolidated)

# Waste generated

1,937



- Waste generated ◆ Waste generation intensity
- \* Three Towa plants
- \* Per sales of JPY 1 million (non-consolidated)

### Ratio of paid leave taken

61.8%

(%) 20-





\* Towa (non-consolidated)

### Water usage

271,269m3



- Water usage ◆ Water use intensity
- \* Three Towa plants
- \* Per sales of JPY 1 million (non-consolidated)

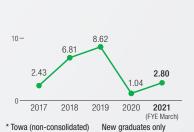
# Ratio of women in management positions

11.1%



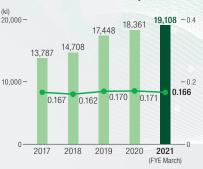
# Employee turnover rate within the first three years

2.80%



### **Energy usage**

19,108 kl



- Energy usage ← Energy use intensity
- \* Three Towa plants
- \* Per sales of JPY 1 million (non-consolidated)

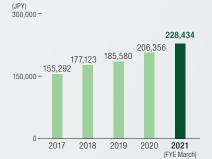
# Ratio of women in new graduate hires

37.38%



### Medical expense reduced

JPY 228,434 million



\* Towa (non-consolidated)

With the generics business as our core, we will increase our corporate value by creating related businesses that contribute to people's health.

Itsuro YOSHIDA

**President and Representative Director** 

# **Endeavoring to develop** products from patients' viewpoints

I would like to express my heartfelt sympathy to all those who have contracted COVID-19 and to their related people. I would also like to extend my deepest gratitude to the healthcare professionals and others, who are working so hard to prevent the spread of the disease.

In June this year, we celebrated our 70th anniversary. I would like to express my heartfelt gratitude to shareholders, investors, and all other stakeholders for their support over the years.

On June 1, 1951, Towa Pharmaceutical Company was established in Osaka-shi and began wholesale and brokerage of pharmaceutical raw ingredients. Later, it was decided to transition to a manufacturer, as the sale of pharmaceutical raw ingredients is directly affected by economic fluctuations, while the operations of manufacturers are relatively stable. On April 19, 1957, TOWA PHARMACEUTICAL CO., LTD. was established for the purpose of wholesale and manufacturing of pharmaceutical products. Initially, we manufactured over-the-counter (OTC) drugs (non-ethical drugs). Although the going was tough, we managed to keep operating smoothly. With the launch of the National Health Insurance System in Japan in 1961, our predecessor predicted that ethical

drugs covered by medical insurance would become the mainstream, and decided to change the business model even though the business at that time was doing well. He steered the business towards the manufacture and sale of ethical drugs. The start of the National Health Insurance System eliminated financial concerns about undergoing treatment for illness. I was still in elementary school at the time, but when I heard that a friend of mine had become ill and had an operation with almost no medical expenses, I realized that everyone, rich and poor alike, would be able to receive treatment when needed. I was just a child, but to this day I still remember feeling that this was going to be a wonderful system.

It was in 1965 that we established a production system for ethical drugs and started manufacturing them. At that time, the term "generic drugs," let alone "generics," was not existent. Our predecessor did everything he could to develop the business based on his strong commitment to "making the world a place where everyone can benefit equally from medical care by supplying inexpensive pharmaceuticals." He also mentioned from time to time that "the business will grow because we pursue what is useful to society." His management policy of contributing to society by selling "more" while maintaining the basic principle of "better products at lower prices" drove the growth of the Company until the beginning of the 2000s.



# Aiming for distinctive generics through the pursuit of added value

In the 2000s, the form of the Company's management changed dramatically. As increasing social security and medical costs became a major social issue, the government accelerated its policy of promoting the use of generics. At that time, we held the top share in the generics market and were also the industry price leader in the industry. However, securing profits was a pain point back then due to intensifying sales competition and NHI price revisions.

I was appointed president in 1996, and I had decided to follow the management policy of my predecessor for the first three years of my tenure. But considering the situation at that time and 10 years into the future, I felt a strong sense of crisis and decided to change the management policy, saying, "If we continue as we are, the survival of our business will be at risk." This marked our switch to the development of distinctive generics through the pursuit of added value and to sales at fair prices that are commensurate with value, and this switch has led to our growth to date. We made our formulation techniques more sophisticated and launched high value-added drugs, and as a result, our generics have a great reputation in healthcare settings as drugs that are easy to handle and easy for patients to take.

In addition, we have established the unique Towa Sales System for pharmaceutical products. It's an approach to selling that consists of two sales systems: a direct sales system based on sales offices and sales agents that deliver directly to medical institutions, and a sales system that delivers through wholesalers. By adopting this system, we have established a mechanism for delivering high value-added products that meet the needs of medical institutions, and by explaining the added value of our products and having doctors and pharmacists understand and accept them, we are able to sell our products at fair prices. At the same time, our MRs, of which we have the largest number in the industry, provide information to the medical frontline, and also collect information, which enables us to quickly share requests from medical institutions for product improvement and enhancement with each department.

In the beginning, when we started to sell our distinctive generics, we received some puzzled comments from sales agents such as, "Your sales method is completely different from the conventional one based on price competition." Towa Pharmaceutical's sales offices were also perplexed at first, but worked hard to provide medical information and sell our products at fair prices, based on the belief that understanding the formulation technology for the drug and its added value will surely be useful to patients. As a result, although we experienced a temporary decline in both sales and profits, the



number of doctors and pharmacists who understood our pharmaceuticals increased, and the volume of pharmaceuticals we supplied grew. In recent years, we have been able to introduce our products to a broader range of doctors and pharmacists through increased collaboration with wholesalers. We will continue to make daily efforts to build relationships of trust with the medical community.

# Pursuing the improvement of pharmaceutical quality by valuing the bond of trust with the medical community

In terms of building relationships of trust, we play a major role not only in sales activities but also in translating voices from the healthcare frontline into the creation of products. As mentioned above, we are also focusing on technological development to enhance the added value of our pharmaceuticals. In addition to gathering feedback from the medical frontline through MRs, we actively share information with R&D and technical departments. We have set up an in-house request review committee, which constantly reviews product improvement proposals and other issues based on information received from MRs. The committee makes more than 200 improvements per year, facilitating the creation of distinctive generics.

RACTAB, an example of our value-added formulation technology, is a proprietary formulation technology that enables us to produce tablets that disintegrate readily, making them easy to take, but that are hard enough to allow them to be subjected to the same treatment as conventional pills. In

addition to this, we are continuing to develop other products. This involves us doing everything from conducting research on what makes a medicine easier to take to designing the packaging design. We will continue to improve and refine our products with the latest technology, constantly updating them to be the latest and greatest at that time.

With regard to our efforts to ensure the quality of our pharmaceutical products, we have been diligently addressing each and every issue as laws and regulations have become stricter and demands from healthcare professionals have increased. For example, under the revised Pharmaceutical Affairs Act, which came into effect in 2005, the number of matters to be included in the marketing approval document for pharmaceutical products increased significantly. At the time, we had a lineup of more than 400 products. We had to carefully prepare the documents for each of them one by one, a task that we only completed in December 2019.

And today, not only do all of our plants perform manufacturing based on procedures that are in compliance with the GMP three principles, but we also provide continuous education and training to our employees, so that each and every one of them is engaged in manufacturing with a high awareness of quality. Furthermore, to manufacture products that meet specifications based on stricter rules, we have actively adopted international standards such as PIC/S GMP and the ICH guidelines to build a system that can eliminate human errors.

As for ensuring the stable supply of pharmaceuticals, we have been steadily making capital expenditure in response to the government's target of having 80% of generics volume share by September 2020. With the new building at the Yamagata Plant having gone into operation in 2018, our annual production capacity in FY2020 was 11.5 billion tablets. This figure includes output from the Osaka and Okayama plants, so there are three plants in total. Through these three plants, we will expand our production capacity to 12.0 billion tablets by the end of FY2021, and again to 14.0 billion tablets by the end of FY2022 in order to meet global demand. In addition, we are planning to construct the 3rd solid formulation building at the Yamagata Plant by the end of FY2023, which will take our production capacity to 17.5 billion tablets from FY2024.

As a result of quality-related wrongdoings that have occurred in the industry, production at other companies has been halted, which has raised concerns in some quarters about the stable supply of pharmaceuticals. We regard this as an issue that affects the trust placed in the entire generics sector, and we will continue to fulfill our mission of ensuring a stable product supply by addressing this issue on an industry-wide basis, which includes the Company.

# Considering how to ensure stable procurement of APIs and intermediates from a long-term perspective

In FY2020, the COVID-19 pandemic had a serious impact on society. We have been carrying out our business with the mission of not interrupting the stable supply of pharmaceutical products at any time, no matter what the situation may be. Although the COVID-19 pandemic did not interfere with our operations to any great extent, it did temporarily raise concerns about the securing of APIs and intermediates, which are essential for the manufacture of pharmaceuticals.

Currently, we procure APIs and intermediates not only from Japan but from all over the world. In response to these concerns, we recognize the need to review our supply chain to guarantee stable procurement from the perspective of "local production for local consumption of products," which is what we consider ideal. From a long-term perspective, we are conducting R&D in the realm of continuous flow precision synthesis technology, which has less environmental impacts and is safer, and using such new technology in manufacturing is something that we are considering. We believe that the practical application of new technology will not only facilitate stable procurement that avoids country risk, but will also lead to the launch of a green sustainable chemistry industry in Japan and the creation of jobs stemming from that.

# **Health-related businesses** paving the way for new growth

The Company has been implementing the 5th Mid-term Business Plan 2021-2023 PROACTIVE II (hereinafter, the "new mid-term plan") since FY2021. Under the 4th Mid-term Business Plan, we achieved our major objectives for net sales, operating income, R&D expenses, capital expenditure, and other items, and we are now making strong progress toward a new stage of growth despite this being a difficult period marked by the COVID-19 pandemic.

Our basic policy is to further evolve our core generics business. But we also intend to expand and grow our business in overseas markets and to develop new health-related businesses.

Toward enhancing generics business, as mentioned above, we will be aiming to "maintain and strengthen a stable product supply system," "work on stable API procurement," "enhance the production capacity," "optimize the Towa Sales System," "maintain and

strengthen the quality assurance system," "offer a broad product lineup," and "manufacture sophisticated products with No.1 total product performance." We will continue to work diligently to address each of these issues.

As for expanding and growing our business in overseas markets, we have been exploring the possibility of establishing a system to supply our valueadded products to overseas markets. This led us to acquire Spain's Pensa (official name, Pensa Investments, S.L.; the current trade name, Towa Pharma International Holdings, S.L.) in January 2020. As a result of this acquisition, our consolidated net sales for the fiscal year ended March 31, 2021 increased by approximately 40%. With the aim of offering products highly regarded in Japan to overseas markets, we will continue to search for latent needs for our value-added products in other countries and territories, and conduct surveys with an eye to expanding our business into regions that we have not yet entered. To sell our products overseas, we are working to establish alliances and cooperative relationships with local companies while taking into consideration factors such as product marketability and risks.

Meanwhile, with regard to the development of new health-related businesses, growing awareness of the importance of extending healthy life expectancy has prompted the construction of a comprehensive community care system to become national government policy, and progress is now being made in this area. Against this backdrop, we are aiming to build a personal health information platform for pre-symptomatic care and disease prevention through digital transformation (DX) facilitated by collaboration with IT companies. In addition to managing and utilizing health information on the platform, we intend to provide health-related products and services ranging from disease treatment and prevention to nursing support.

Specifically, we will provide OTC drugs and medication support tools, and also develop health foods, supplements, and health promotion tools. One such product is "comuoon," an interactive support device that helps address problems in society related to hearing. It is a desktop conversation support system that converts the voice of the person talking into one with a level of sound quality that is easier to hear, and is expected to be used in medical institutions, nursing homes, and local communities. Early detection of hearing loss and maintenance of hearing quality is expected to help prevent mild cognitive impairment (MCI) and dementia, and this is in line with our policy of contributing to health from broad perspectives. And to reduce the burden on those engaged in nursing care, rehabilitation, and other similar services, we have taken a stake in a manufacturer of care welfare equipment that manufactures a product called Muscle Suit, a wearable work support robot. It is our hope that we can grow our

health-related businesses and contribute to the revitalization of local communities by providing society with products based on innovative technologies.

And as another health-related business, we have entered the testing business by making Protosera Inc., a provider of testing services, a subsidiary. Since this business has great social significance in terms of disease prevention, we will aim to get it off the ground as part of our efforts to develop new health-related businesses, one of the basic policies contained in the new mid-term plan.

# Focusing on the development and utilization of each individual human resource

Going forward, it will be important for us to further strengthen our human resource base so as to steadily implement the new mid-term plan and achieve sustainable growth over the medium to long term. In this regard, we have a long history, from our founding to the present day, of fostering a corporate culture that values human resources.

For example, this is what I felt when we acquired Mect Co., Ltd.'s Tohoku plant back in 1998. For starters, I visited the plant in September of that year, when the acquisition was being discussed. It was around three months after operations at the plant had been suspended, and at that time it was hard to see how the company itself could survive. The corridor leading to the factory floor had been kept clean and tidy. On the shop floor, the machinery and equipment were arranged in a neat and orderly fashion. It had been well preserved, maintained, and managed.

In front of the clean manufacturing area, one of the employees turned to me and said: "We are so grateful to have been able to work here for so long that until the final decision [about the acquisition] is reached, we are making sure the equipment can be restarted immediately at any time." I still remember those words. This was one of the main reasons we decided to go ahead with the acquisition.

After the acquisition, but before we started manufacturing medicines at the plant, which was now known as our Yamagata Plant (and which was later renamed the Yamagata 1st Plant), we interviewed all 108 employees to confirm their individual intentions. Through these interviews, we realized that everyone was serious and sincere, and we decided that the plant could be operated by these 107 people, who included managers (one person had declined to be hired). So, we didn't send any of our officers or employees to work there. What we did was have me visit the factory in Yamagata every month, and gradually adjust the pay

structure over a period of 10 years to match ours. Factory operation went smoothly and has continued to this day. This is an example of a situation in which we realized the importance of human resources.

To strengthen our human resource base, the new mid-term plan calls for "making job satisfaction and fostering talented human resources," and we are therefore working from various angles on human resource development, career-path enrichment, and job satisfaction. In the area of career development, in particular, we are endeavoring to develop each employee according to their abilities and aptitudes from a cross-organizational perspective, namely one that is not limited to each department, while also taking into account the wishes of the individual with respect to building their career from the time they join the Company until their retirement.

The word "PROACTIVE," which we have used as the name of the new mid-term plan, encompasses such meanings as enthusiastic, autonomous, and visionary. The name represents our hope that as we continue to expand our business, each and every one of our employees will be able to anticipate possible future changes and risks and take the necessary measures in advance to expand the scope of their work enthusiastically and autonomously.

# Becoming a company that will continue to safeguard genuine smiles even after 100 years

In June this year, we celebrated our 70th anniversary. Taking this as an opportunity to look back on our history, I believe that corporate management must look ahead 10 years, 20 years, and even 100 years into the future and beyond. As the birthrate declines and the population ages, how will Japanese society have changed 100 years from now, and what will be important then? Also, what should we be aiming to become as a company in the future? As a project to mark our 70th anniversary, we are going to determine what we should do right now for the sake of ourselves a century from now.

As part of that, what we have emphasized more than anything else are "genuine smiles" and "people's health," as stated in our vision. From a global perspective, Japan today is a free, peaceful, and prosperous country where the dignity and human rights of each and every citizen are respected. As long as we exist, we will continue to pursue the realization of "genuine smiles" and "people's health," and we believe it is important to make the ability to contribute to the continued preservation of this prosperous country an unwavering part of our

management policy in every era.

In addition, we in the Towa Group believe that it is important to continue to contribute to local communities and people around the world as a public institution in society.

As an example of our contribution to local communities, I'd like to tell you about our future-oriented initiatives in Mongolia.

By chance, more than 10 years ago we started trading pharmaceuticals, and when I researched the country's situation, I found that Mongolia had very few unique industries to support its economy, which along with the desertification of its land was a major problem for the country.

In the vast grasslands of Mongolia, licorice grows wild everywhere. Licorice is frequently used as a natural food additive and is also used in traditional Chinese medicine. A pharmaceutical ingredient called glycyrrhizic acid can also be extracted from it, so it's an incredibly valuable plant. In recent years, licorice has been designated by the national government as a protected plant because its uncontrolled picking contributes to desertification. However, the problem of over-picking doesn't appear to have disappeared completely, and desertification remains a problem along with the depletion of underground resources through mining.

Thinking that we could do something to help, we secured a vast plain several years ago and have been trying to grow licorice, as an herbal medicine, there.

Licorice requires at least five years from planting to harvesting if it is to be used in Chinese medicine. It takes a lot of time and effort to cultivate it, but we hope that this initiative will contribute to the revitalization of local communities by providing employment opportunities for the local people and curtailing the desertification of the country. Although it's only a small project, we believe that it can also play a part in producing the "genuine smiles" that we wish to create as a Company. If all goes well, after planting, managing, and harvesting the licorice, we will be able to dry, cut, and sell it, and we hope to contribute to the industrial development of Mongolia by localizing the process of extracting and selling it to make medicines.

Considering its profitability as a business, I doubt this project will last more than five years. That is why we are calling this initiative the Mongolia 100-Year Plan.

Being a company, it is obviously important to pursue economic value. And from the perspective of sustainable corporate growth, I believe, after considering the value of the existence of a company, that the Towa Group needs to develop on a scale that meets the needs of the people of the era and region in which it operates.

Our priority is to be a company that can continue to provide value to all the people connected with the Towa Group.

By doing that, I believe that the value of the Company will be recognized and that earnings will follow.

In the future, we will achieve sustainable growth while aiming to be a company that can contribute more than ever to people's health. We would like to ask for your continued support in these endeavors.



# **Our Value Creation Process**

To address social issues, Towa Group has created value by allocating its business capitals to every business that contributes to people's health. We will contribute to the health of all people and help them achieve a genuine smile based on the "5th Mid-term Business Plan 2021-2023 PROACTIVE II."

# **INPUT Business Capital**



**Social Issues** 

Extension of healthy

life expectancy and

disease prevention

Production of

pharmaceutical products

Quality assurance and stable supply

of pharmaceutical

Better accessibility

healthcare services

to healthcare services

Improvement of

working

environment

products

to primary

Application of advanced technology

high-quality

# Financial capital

- Total assets: JPY 245.6 billion (consolidated)
- Net assets: JPY 116.5 billion (consolidated)

# Manufactured capital

- Production sites: 8 (7 in Japan [including Towa's 3 plants], 1 in Europe)
- Production capacity (Towa's 3 plants): 11.5 billion tablets (tablets and capsules)
- Production facilities for various dosage forms

# Intellectual capital

- R&D offices: 7 (6 in Japan, 1 in Europe)
- R&D Expenditure: JPY 35 billion and more (Accumulative) (FY2021-FY2023)
- API synthesis process knowhow

# **Human capital**

- Employees: 3,456 (consolidated)
- Consolidated subsidiaries: 11 (3 in Japan, 8 in overseas countries)
- Qualified pharmacists: 234 (consolidated in Japan)
- MRs: 800 (consolidated in Japan)

### Social and relationship capital

- Collaborate with business partners including raw material manufacturers, medical products distributors and agents
- Medical institutions coverage ratio (Towa) Hospitals 89.2% Dispensing pharmacies 95.2%

# **Natural capital**

- Energy input (crude oil equivalent, Towa's 3 plants) 19,108 kl
- Water consumption
- (Towa's 3 plants)

271,269 m<sup>3</sup>

Towa Quality

**Manufacturing sophisticated products** with No. 1 total product performance

> 5th Mid-term **Business Plan** 2021-2023 **PROACTIVE II**

Corporate Governance (Compliance and Risk Management)

**Our Commitments (T-SMILE)** 

**Towa Philosophy** 

Foundations supporting value creation

### OUTCOME

# **Towa Group's** value proposition

We will support everyone who cares about good health to live a healthy lifestyle by making it easier to be and stay healthy as part of everyday life.

**Enhancing generics** business as a core

**Expanding and** growing business in overseas market

**Entering new** health-related business

> Creating technology innovations and product values

Making job satisfaction and fostering talented human resources

# **Social Impact**

**Extending healthy** life expectancy of more than 7 billion people around the world

**Controlling** healthcare costs of the government, administrative agencies, and local communities

Maintaining sustainable healthcare system

# Genuine smiles

People's health

# **External Environment Surrounding Towa Group**

# Entering the era where measures for new challenges are required despite having achieved the government's generics volume share target

In recent years, generics have come to play an increasingly vital role in the society. Under the "Basic Policy on Economic and Fiscal Management and Reform 2017" approved by the Cabinet in 2017, the government has set a target to increase the generics volume share to 80% by September 2020. In response to this, the generics industry including Towa has focused on enhancing production capacity and ensuring stable supply. The results of analysis issued by the Japan Generic Medicines Association show the volume share reached 80.1% in the fourth guarter of fiscal 2020 (January to March 2021) and indicated the target of 80% was achieved.

Furthermore, in the "Basic Policy on Economic and Fiscal Management and Reform 2020," the government says to "protect people's lives, livelihoods, jobs, and businesses" to achieve the "New Future in the post-pandemic." The government also envisions achieving a "New Normal Lifestyle" by a full speed revolution at a stroke that would take 10 years under normal circumstances. Achieving a high-quality economic society in the "New Normal Lifestyle" is set as a goal for the New Future in the post-pandemic.

Meanwhile, under the "Future Social Security Reform-Looking to 2040" issued by the Ministry of Health, Labour and Welfare, the government aims to realize a society where everyone can work longer and more energetically by solving issues such as "diverse employment and social participation," "extension of healthy life expectancy" and "medical and welfare service reforms." Generics are playing a greater role under these government policies and we are expected to contribute to extending healthy life expectancy by forming an infrastructure to create ideal local communities and providing necessary health promotion services to people in need of them.

# There is a pressing need of industry-wide initiative to restore confidence in generics which has been eroded

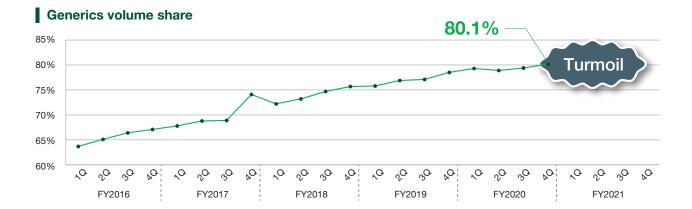
While the generics volume share has steadily risen, the recent quality problems in the generics industry have affected the entire industry. Public confidence in generics built by the industry so far is declining. As the drug companies involved in quality problems suspended their operations, the industry as a whole has failed to fulfill its responsibilities for stable supply. As a result, the generics market is in turmoil and the future of generics companies is worrisome.

Under such circumstances, the Ministry of Health, Labour and Welfare mentioned that the industry would never gain understanding from patients and healthcare professionals only by setting new numerical targets for generics. In order to regain

public confidence in generics, the entire industry shall implement measures for ensuring a stable supply based on thorough manufacturing and quality management.

While still pursuing Towa Quality, we will make the utmost efforts to restore public confidence in the industry by enhancing the product lineup needed and maintaining and strengthening the system for stable supply/quality assurance as well as for information provision.

Our activities on health-related business conform to this direction and we will strive to become a valued company that contributes to the society.



# **Towa Group's Capital**

Towa focuses on creating value across its Group by working sincerely to solve social issues while leveraging various capitals gained in the past business operations. By solving issues including the extension of healthy life expectancy, we will contribute to the health of people around the world.



# Financial capital

- Net assets (consolidated)
- .IPY 245.6 hillion
- Total assets (consolidated)
- JPY 116.5 billion

Total assets at the end of FY2020 increased JPY 15,651 million YoY to JPY 245,668 million. Net assets at the end of FY2020 increased JPY 11,934 million YoY to JPY 116,599 million. As a result, capital-to-asset ratio was 47.5% at the end of the fiscal year under review.



# **Manufactured capital**

- Production sites: 8 (7 in Japan [including Towa's 3 plants], 1 in Europe)
- Production capacity (Towa's 3 plants):
  - 11.5 billion tablets (tablets and capsules)
- Production facilities for various dosage forms

Towa Group has 8 production bases in total, comprising of 7 in Japan and 1 in Catalonia, Spain. Production capacity stands at 11.5 billion tablets for tablets and capsules produced at Towa's 3 main plants. Our subsidiaries produce ointment, soft capsules, etc. and the Group is distinguished by its capacity to produce diverse dosage forms.



# Intellectual capital

- Research hubs: 7 (6 in Japan, 1 in Europe)
- R&D Expenditure: JPY 35 billion and more (Accumulative) (FY2021-FY2023)
- API synthesis process knowhow

R&D is conducted in 7 hubs in total comprising 6 in Japan and 1 in Europe. Target R&D expenditure from FY2021 to FY2013 is JPY 35.0 billion (accumulative). This covers the leading-edge research on API synthesis including molecular control technology.



# **Human capital**

- Employees: 3,456 (consolidated)
- Consolidated subsidiaries: 11 (3 in Japan, 8 in overseas countries)
- Qualified pharmacists: 234 (consolidated in Japan)
- MRs: 800 (consolidated in Japan)

Towa Group hires 800 MRs and 234 qualified pharmacists (both consolidated in Japan). In addition, we have introduced an internal qualification system for business operations (experts, etc.) to nurture professionals.



# Social and relationship capital

- Collaborate with business partners including raw material manufacturers, medical products distributors, and agents
- Medical institutions coverage ratio (Towa) Hospitals 89.2% Dispensing pharmacies 95.2%

We engage in nationwide marketing activities through 71 sales offices, 31 agents at 60 sites, and medical products distributors, among others, in Japan. Towa has a high coverage ratio of medical institutions: 89.2% for hospitals and 95.2% for dispensing pharmacies.



# **Natural** capital

- Energy input (crude oil equivalent, Towa's 3 plants)
- 19,108 kl
- Water consumption (Towa's 3 plants)
- 271,269 m<sup>3</sup>

We use good quality water and energy resources to produce high-quality pharmaceutical products. In this regard, from an environmental perspective, we manage chemical substances properly, enhance the plants' water discharge and air emission systems, take energysaving measures, and make other efforts.

# **Looking Back on Previous Mid-term Business Plan**

# **Previous Mid-term** Business Plan 2018-2020

# **PROACTIVE**

Under the 4th Mid-term Business Plan 2018-2020 PROACTIVE, we steadily expanded our domestic generics business to ensure its steady growth and continuation of stable supply. Among other things, we increased production capacity at three plants to ensure the continuation of stable supply.

In addition, we continued research on fundamental technologies and practical applications for the further evolution of product quality. And based on our policy of entering new markets, we began full-scale entry into overseas markets. Furthermore, with an eye to the creation of new businesses, we endeavored to launch IT-centered services.



### Basic Policy (1)

Steady growth of domestic generic business / continuation of stable supply

We expanded generics business in Japan by newly launching 76 items of 30 APIs during the three years to FY2020. In addition, we concluded a joint sales agreement with Celltrion Healthcare Japan Co., Ltd., and made a start in selling biosimilar products. Furthermore, we expanded manufacturing facilities to ensure the continuation of stable supply, and have achieved a production capacity target of 11.5 billion tablets\* per year at the three plants in Osaka, Okayama, and Yamagata. \*Production capacity of tablets and capsules

### Basic Policy (2)

**Further evolution of product** quality for sustainable growth With the aim of further improving product quality, we continued research on fundamental technologies and practical applications for tackling various issues. In addition, we conducted research on molecular control technology, as well as continuous flow precision synthesis and integrated continuous manufacturing, as means of achieving green sustainable chemistry.

### Basic Policy (3)

Entry to new markets and creation of new businesses As a means of entering new markets, we began full-scale entry into overseas markets by making Pensa Investments, S.L. (current trade name, Towa Pharma International Holdings, S.L.; hereinafter, "Towa HD") a wholly-owned subsidiary. In the area of the creation of new businesses, we established T Square Solutions Co., Ltd. as a joint venture with TIS Co., Ltd. in order to provide IT-centered services that contribute to the realization of a society in harmony with local communities. Furthermore, we acquired Protosera Inc. as a subsidiary and launched a testing service business. Besides these initiatives, we also began developing new health-related products and services including launching interactive support devices that convert voice into sound that is easy to hear and, and medication support tools to improve drug adherence.

### Major Objectives

Operating income R&D expenditure Capital investment Capital-to-asset ratio Net sales **Dividend policy** Initial target of JPY 26.0 billion Stable payout Targets JPY 30.0 billion JPY 20.0 billion or more 50% or higher JPY 100.0 billion Product development plan aiming for stable launches Improvement of products in response to requests from healthcare professionals and or more
From May 2019 or more Improvement of financial or more Modified target stability JPY 40.0 billion Achievements JPY 52.0 billion JPY 27.1 billion JPY 22.6 billion JPY 154.9 billion 47.5% Stable dividend Net sales (consolidated) (fiscal year) Capital-to-asset ratio Dividend per share Operating income (consolidated) (fiscal year) Capital investment R&D expenditure (fiscal year) (fiscal year) (consolidated) (fiscal year) (consolidated) (fiscal year) JPY 105.1 billion (2018) JPY 110.4 billion (2019) JPY 154.9 billion (2020) 48.6% (2018) 45.5% (2019) 47.5% (2020) JPY 35.8 yen (2018) JPY 44.0 yen (2019) JPY 44.0 yen (2020) JPY 16.0 billion (2018) JPY 16.1 billion (2019) JPY 19.9 billion (2020) JPY 7.9 billion (2018) JPY 8.6 billion (2019) JPY 10.6 billion (2020) JPY 6.0 billion (2018) JPY 6.2 billion (2019) JPY 10.4 billion (2020)

- 1) Towa HD included in consolidation in FY2020
- 2) Stock split on April 1, 2019

# **New Mid-term Business Plan**

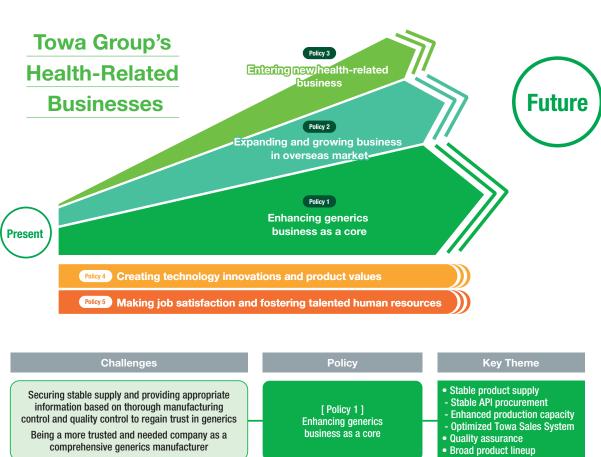
# **Mid-term Business Plan** 2021-2023

# PROACTIVE II

Under our 5th Mid-term Business Plan 2021-2023 PROACTIVE II (hereinafter, the "5th Mid-term Plan"), the Group will be developing health-related businesses in line with five policies as shown in the diagram below. With our domestic generics business, which is our core business, we will be aiming to make an even greater contribution as we move forward into the future. And as for overseas markets, we will be expanding the number of countries and territories in which we offer the

Group's products. Furthermore, in the realm of new health-related businesses, we are embarking on a new era, so will be steadily doing what's necessary as we look ahead to the future.

To implement these policies, it will be important to continuously create technology innovations and product values, and we will therefore be continuously working to enhance job satisfaction and foster talented human resources.



 Manufacturing sophisticated products with No. 1 total [Policy 2] product performance Delivering high-quality, value-added generics to **Expanding and growing business** contribute to the health of people around the world Contributing to the realization of healthcare and nursing care for society with a long and healthy life expectancy Entry to testing service business Entering new health-related and also to society that shifts from medical care to care of pre-symptomatic disease and prevention Contributing to society by constantly supplying the Towa Creating technology innovations and product values Quality products and achieving sustainable growth Continuing to be an ever growing company that provides [Policy 5] job satisfaction to each and every employee through Making job satisfaction and growth of both the company and its employees fostering talented human resources



# Enhancing generics business as a core

# Stable Supply System

To maintain and strengthen a stable supply system, we will emphasize the perspective of supply chain management, and will share information and encourage cooperation across departments to optimize the entire system. In this way, we will go ahead with risk-adapted initiatives. Specifically, we will

provide Towa products to medical institutions, pharmacies, and patients, who need the products, by increasing production capacity through our three-plant production structure and by optimizing the Towa Sales System. In particular, we will be pursuing initiatives that take into account the risks in API procurement.

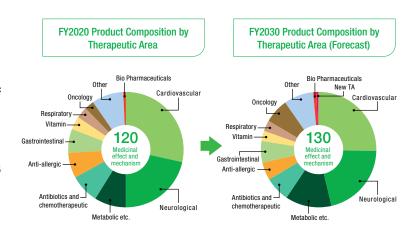
# **Quality Assurance System**

Throughout manufacturing and quality control processes, we will comply with GMP, GQP, and GVP ministerial ordinances and the GDP guidelines to maintain and strengthen our quality assurance system. In every process from the acceptance of APIs to the testing of intermediate products, the

testing of finished products, product shipment decision-making by plants, and product shipment decision-making by the HQ QA Dept, we will strengthen our management systems and schemes, and continue to work to ensure reliable quality and safety.

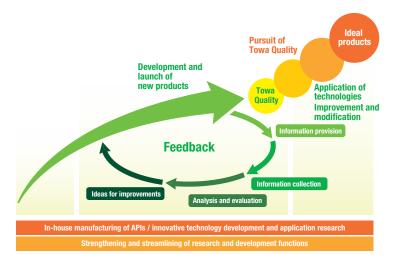
# **Broad Product Lineup**

We will put together a generic-drug product lineup with a focus on medicines deemed necessary for future medicinal treatment. We established lineups of products in a broader range of therapeutic areas, and conducted joint sales of Infliximab BS as a steppingstone of entry into the biosimilar market. In addition, we will be taking on challenges in diversified areas such as drug re-positioning with iPS drug discovery, development of Rivastiamine transdermal system twice-aweek medicine, etc.



# Manufacturing sophisticated products with No. 1 total product performance

Manufacture of sophisticated products with No. 1 total product performance refers to our initiatives in providing the market with products characterized by "Towa Quality" that are desired and needed by customers. This guarantees the quality of the products that we supply under thorough quality control. We are constantly using the latest technologies to improve and modify the quality of the products, and we are constantly upgrading the products to the latest and best. We are strengthening and streamlining research and development functions through investment in facilities and equipment.





# Expanding and growing business in overseas market

We will strive for the sustainable growth of our business by introducing new products in Europe and the United States, mainly through Towa HD, which we acquired in 2020. At the same time, we will develop Towa Quality products meeting patients' needs overseas. Furthermore, we will explore market opportunities in new countries/regions.





# **Entering new health-related business**

As one of our challenges, we aim for creating a future that provides full coverage from medical care to care of pre-symptomatic disease and prevention for society with a long and healthy life expectancy. In line with our vision of contributing to people's health, we will work to create new health-related businesses that are suited to the new medical system, while acquiring new techniques and integrating them with completely new knowledge and technologies. Specifically, we will help build an infrastructure to create ideal local communities, and contribute to extending healthy life expectancy by providing necessary health promotion services to people in need of them. Among our key measures, we will be launching testing services for determining disease risks, expanding the KENTO Healthcare Science Center, which opened in 2019 to conduct joint research with the National Cerebral and Cardiovascular Center to extend healthy life expectancy, and collecting/ utilizing information obtained from testing to provide appropriate health-related services.

Kev measures

- · Building a foundation for extending healthy life expectancy by utilizing data
- Contributing to the Comprehensive Community Care System
- Further enhancing lineup of products and services to maintain and improve health
- · Entering disease risk testing service business
- Core business • Creating synergies between and with existing businesses Generics Sports facilities etc City offices / community centers OTC drugs Medication support tools Frail Disease Health foods Communication Supplements support Individual Health Information Platform Health promoting tools Nursing support

Contributing to forming of infrastructure for the creation of ideal local communities Providing necessary health promotion services to people who need them and contributing to the extension of healthy life expectancy



# Creating technology innovations and product values

To contribute to society by constantly supplying the Towa Quality products and achieving sustainable growth as a company, we will continue to work on creating technology innovations and product values. In particular, we will pursue technological innovation in API technologies such as molecular control technology, chiral synthesis technology, and

continuous-flow precision synthesis, in formulation technologies, such as ones that allow the production of OD tablets that are easy to take, and in manufacturing technologies for continuous production. By conducting joint research aimed at obtaining a new indication for Bromocriptine, we will be aiming to create new product value.

### Establishment of molecular control technology

- Freely controlling crystal form and particle size of APIs
  - → Contribution to the development of value added products

### Establishment of chiral synthesis technology

Enabling efficient API synthesis

### Development of continuous flow precision synthesis

 Pursuing green sustainable chemistry with wastes reductions and low CO2 emissions as key initiatives

### Manufacturing Technology

Establishment of technology to monitor products in real time (PAT: Process Analytical Technology)

Application to integrated continuous manufacturing system

- Production carried out under an integrated flow leading to labor saving
- Smaller manufacturing facilities and occupation areas

### Pursuing OD tablets that are easy to take

- Further improvement of RACTAB
  - → Masking technology to reduce bitterness, miniaturization of tablets and better oral disintegration

### Realization of stable formulations

- Development of formulations stable in term of heat, light, moisture and oxygen
- Assurance of expiration period of formulations for three years and more

### Joint research aimed at obtaining a new indication for Bromocriptine

Clinical trials for familial Alzheimer's disease started

### Development of new Rivastigmine formulation

- Development of transdermal system twice-a-week medicine
- Hope for reducing the burdens on patients, their families, and caregivers
- Phase III clinical trials planned for the summer 2021



# Making job satisfaction and fostering talented human resources

As the growth of employees leads to the strengthening of corporate fundamentals and facilitates growth corresponding to change, we are working to establish an environment for the enhancement of corporate fundamentals. In connection with this, we are aiming to create workplaces where there is respect for

diversity in work styles and motivation for each and every employee. We also view our employees as vital investment resources and assets for the Company, and are stepping up fostering talented human resources who can make an impact as we pursue growth.

# **Major Objectives**

### **Net sales**

JPY 200.0 billion (consolidated) JPY 150.0 billion (non-consolidated)

Achievement of single-year sales target

### Operating income (accumulative)

### JPY 57.0 billion or more

Achieving cumulative operating income for the period to invest in sustainable growth and return profits to shareholders

# R&D expenditure (accumulative)

# JPY 35.0 billion or more

Lineup of needed products and improvement of products based on the requests from medical institutions and patients

# Capital investment (accumulative)

### JPY 75.0 billion or more

Investment in strengthening and streamlining our production facilities and R&D functions to maintain and strengthen our quality assurance and stable supply systems

### **Dividend policy**

### Stable dividend

Ensuring stable dividends and returning profits to shareholders through improved corporate value

# **Businesses Pursued by Towa Group**

Based on our vision: "We contribute to people's health; we are dedicated to people's genuine smiles," Towa Group contributes to people's health by creating superior products and services. Through our corporate activities, we aim to be a company that is valued and needed by patients, healthcare professionals, local communities, and others.

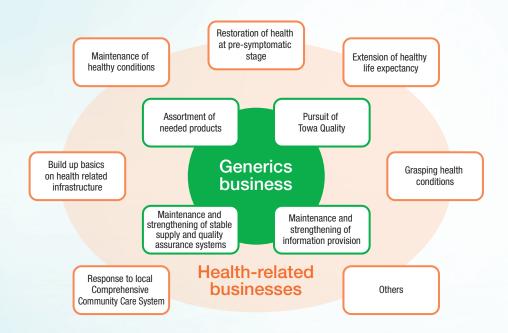
Under the 5th Mid-Term Business Plan, we will maintain our vision while expanding the scope of our business to include health-related businesses. Nevertheless, our core generics business in Japan and overseas will maintain its central role in our operations.

In this core business, we will further strengthen and utilize the results of all the efforts we have made so far. Based on the premise of "pursuit of Towa quality," we will strengthen our "assortment of needed products" to meet the demands of society as a

comprehensive generics manufacturer. In addition, we will maintain and strengthen our system to provide a stable supply of products that meet quality standards and to deliver information on safety and quality in a timely and accurate manner.

Furthermore, the Group will pursue corporate activities to contribute to the creation of new health-related businesses. Through these businesses, we will help form an infrastructure to create ideal local communities, and contribute to extending healthy life expectancy by providing necessary health promotion services to people in need of them.

And with regard to the Sustainable Development Goals (SDGs), international objectives to be achieved by 2030, we aim to contribute mainly to the attainment of Goal No.3 "Good Health and Wellbeing" along with the other goals.



With generics business set as our core, expansion of all health-related businesses contributing to people's health



In response to the international initiatives of SDGs to be achieved by 2030, we will focus on the Goal No. 3 "Good Health and Well-being" along with other goals.













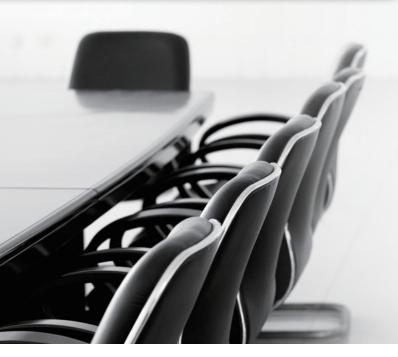










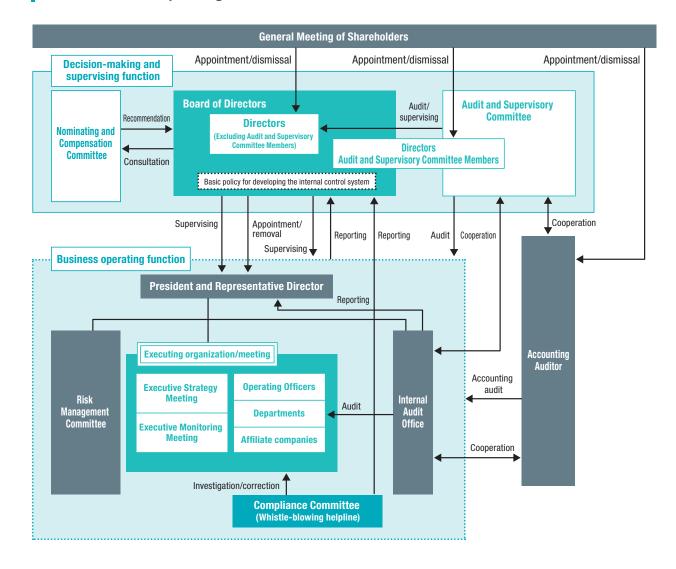


### **Basic approach**

As an important issue, we focus on implementing a better corporate governance. By conducting business strictly in compliance with the ethical standard and improving transparency of the management, we continuously raise the corporate value for the shareholders. To achieve this, we endeavor to respect and protect shareholders' rights as well as establish and maintain good relationships with all of our stakeholders including shareholders. At the same time, we continuously make efforts to achieve our social missions as a healthcare company by focusing on maintaining and improving corporate ethics and ethical standards of officers and employees.

This policy also applies to the Towa Group companies. Each of the Group companies fulfills required roles and obligations to increase the corporate value of the Towa Group as a whole.

### Overview of the corporate governance structure



# **Enhancement of the corporate** governance structure

Towa continuously makes efforts to enhance its corporate governance structure. Towa is a company with an audit and supervisory committee system. The Company is governed mainly by the Board of Directors consisting of seven Directors and the Audit and Supervisory Committee consisting of four Directors who are Audit and Supervisory Committee Members (including three Outside Directors).

One of the main roles of the Board of Directors is to make decisions on mid- to long-term management policies and important operations. Their important roles also include resolving the basic policy of the internal control system and supervising Directors' business execution. To ensure the effectiveness of such decision making and supervision, we need to reduce the number of Directors, separate Directors and Operating Officers and clarify their roles, and build an environment that encourages Outside Directors to express their opinions.

Under these policies, Towa has made several efforts. This includes the transition to audit and supervisory committee system, introduction of midto long-term performance-based stock compensation system, establishment of the Nominating and Compensation Committee, enhancement of functions of Outside Directors, and stimulation of the Board of Directors. Going forward, Towa will continue to focus on enhancing the corporate governance structure.

### **Board of Directors**

The Board of Directors of the Company is chaired by the Representative Director. Meetings of the Board of Directors are held monthly in principle. The Board discusses important management matters at the meetings and makes decisions promptly. With regard to business execution, the Company has introduced an operating officer system and built a governance structure to clarify the Directors' responsibilities. With the structure, Operating Officers bear the responsibility for business execution while the Board of Directors focuses on decision making and supervision of management issues.

# **Audit and Supervisory Committee**

The Audit and Supervisory Committee of the Company consists of four members including three Outside Audit and Supervisory Committee Members. Audit and Supervisory Committee Members conduct effective audits according to audit plans formulated by the Audit and Supervisory Committee. Specifically, they attend important meetings such as the Board of Directors meetings; receive reports from Directors, Operating Officers, employees, and the Accounting Auditor; and conduct on-site audits of major offices.

# **Nominating and Compensation** Committee

The Nominating and Compensation Committee of the Company is chaired by the Representative Director and more than half of whose members are Independent Outside Directors. The purpose of the Nominating and Compensation Committee is to deliberate matters on the appointment and dismissal of Directors and Operating Officers, nomination of candidates, succession planning, and compensation in consultation with the Board of Directors, and to make recommendations to the Board of Directors.

# Analysis and evaluation of the effectiveness of the Board of Directors as a whole

The Company conducted a self-evaluate survey for Directors from February to March 2021 to analyze and evaluate the effectiveness of the Board of Directors. The survey used a questionnaire consisting of 19 questions including those on the structure, operations, and discussions of the Board of Directors. Results of the survey were reported at the meeting of the Board of Directors held on April

Although the survey showed no significant issues on the effectiveness as a whole, it reminded us that we need to discuss mid- to long-term management challenges. Based on those results of the evaluation. the Company will further endeavor to enhance the effectiveness of the Board of Directors.

# **Roles and independence of Outside Directors**

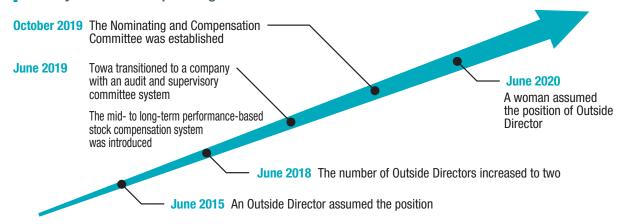
The Company believes that fair and efficient corporate management can be achieved through Outside Directors' advice and opinions on sound and efficient management. The Company has established the Nominating and Compensation Committee as an advisory body to the Board of Directors in order to further enhance and strengthen the corporate governance structure. In particular, the committee contributes to appropriately providing the Outside Directors with opportunities for involvement and advice so as to increase the objectivity and transparency of the decisionmaking process on the matters such as appointment/ dismissal and compensation for Directors and other

officers. Currently, all of the Outside Directors are Audit and Supervisory Committee Members. The Company has built a system to help them fulfill their duties as Audit and Supervisory Committee Members. Specifically, agenda items of the Board of Directors are sent to them in advance by the General Affairs Department, the administrative office of the Board of Directors, so that the Members can consider matters to be discussed thoughtfully. In addition, they are provided necessary support by the assistant staff of the Audit and Supervisory Committee as well as reports and explanations on important matters by the full-time Audit and Supervisory Committee Member.

### Reasons for nomination of Outside Directors

Name/position	Reasons for nomination	Attendance	
Norikazu Eiki Outside Director (Audit and Supervisory Committee Member) Assumed the office in June 2019	Norikazu Eiki has wide-ranging insights and extensive experience at a global company, and the Company expects that his advice and opinions will promote sound, efficient and objective management, for which reason it has appointed him as an Outside Director.	Board of Directors meetings (held 13 times) 100%	Audit and Supervisory Committee (held 13 times) 100%
Kaori Oishi Outside Director (Audit and Supervisory Committee Member) Assumed the office in June 2020	Kaori Oishi has expertise and extensive experience as an attorney-at-law.  The Company expects that her advice and opinions based on such a background will ensure sound corporate management and promote compliance management, for which reason it has appointed her as an Outside Director.	Board of Directors meetings (held 10 times) 100%	Audit and Supervisory Committee (held 10 times) 100%
Kenryo Goto Outside Director (Audit and Supervisory Committee Member) Assumed the office in June 2021	Kenryo Goto has expertise in fields including finance and accounting as a certified public accountant and extensive experience as a corporate manager of an audit firm. The Company expects that his advice and opinions based on such a background will improve the transparency and objectivity of management, for which reason it has appointed him as an Outside Director.	_	_

### History of Towa's corporate governance



# Compensation for officers

The Company formulated the basic policy for the determination of Directors' compensation. Under the policy, compensation shall:

- · Contribute to secure talented people to ensure "Towa Group Philosophy," "Our Commitments," "Corporate Policy," and "The Charter of Corporate Behaviors in Towa Group,"
- · Be linked with clear targets for corporate and individual performance to increase Directors' motivation and morale as they perform their duties,
- · Help to raise awareness of the contribution to improving mid- to long-term performance and corporate value, and
- · Be determined with a focus on raising awareness of sharing interests with shareholders and shareholdercentered management.

With the basic policy above, the Company introduced the mid- to long-term performance-based stock

compensation system for Directors (excluding Outside Directors and Directors who are Audit and Supervisory Committee Members). This introduction was made to further clarify the link between compensation and the Company's mid- to long-term performance and shareholder value, as well as to improve corporate value over the medium to long term by granting incentives while raising Directors' awareness of contribution to the improvement of corporate value and shareholder-centered management.

In addition, the Company has established the Nominating and Compensation Committee as an advisory body to the Board of Directors with the aim of increasing the objectivity and transparency of the decision-making process of compensation for Directors or other matters as well as further enhancing and strengthening the corporate governance structure.

# Total amount of compensation for Directors

Position	Total amount of compensation (in millions of yen)	Amount of compensation by type (in millions of yen)				
		Basic compensation	Annual bonuses (based on individual performance)	Performance-based compensation		Number of eligible
				Monetary compensation	Non-monetary compensation	officers
Directors (Excluding Audit and Supervisory Committee Members)	175	103	13	48	10	3
Directors (Audit and Supervisory Committee Members) (of which Outside Directors)	47 (24)	47 (24)	_ (—)	_ (—)	_ (—)	4 (3)
Total (of which Outside Directors)	223 (24)	151 (24)	13 (—)	48 (—)	10 (—)	7 (3)

# **Cross-shareholdings**

The Company may hold cross-shareholdings upon request from a business partner as a means to build, maintain, and strengthen long-term and stable transactional relationships with the business partner. In that case, however, the Company holds cross-shareholdings only when it is deemed that holding of such shares will contribute to the enhancement of its corporate value over the medium to long term.

Whether to hold cross-shareholdings is determined yearly by the Board of Directors with consideration of mid- to long-term economic rationality and future outlook. The Company exercises its voting rights of cross-shareholdings appropriately after closely examining the proposals and determining whether the holding of such shares will contribute to the enhancement of shareholder value. The Company does not make an affirmative determination on proposals that may damage shareholder value. In addition, the Company will be against proposals of appointment of Directors and other officers who committed any antisocial act or violation of legal obligations.

If a cross-shareholder expresses an intention to sell the shares, the Company does not hinder the sale or other acts. When conducting transactions with crossshareholders, the Company will thoughtfully examine the economic rationality of those transactions, just as with those with other business partners.

# Dialogues with stakeholders

The Company discloses the information on its management strategies and finance/performance status, among other matters, to shareholders, investors, and other stakeholders through investor relations activities in an appropriate and timely manner. In addition, the Company emphasizes constructive dialogues with stakeholders including shareholders and investors so as to deliver opinions, requests, and other similar things obtained from such dialogues to the Board of Directors for the improvement of corporate value.

The Company recognizes the importance of appropriate collaboration with not only shareholders and investors but also other stakeholders including patients, healthcare professionals, business partners, local communities, and employees. For creating corporate value, we are committed to disclosing information in an appropriate and timely manner to all of our stakeholders in order to maintain good and smooth relationships with them.

# **Risk Management**

# Basic approach to risk management

To ensure company-wide risk management, the Company has formulated the "Basic Regulations for Risk Management," which shall be complied with by all the departments, officers, and employees of the Towa Group. It is critical for the Group's continuation and growth to respond to the risks surrounding the Group promptly and appropriately. We aim to prevent risks as well as to minimize the loss of stakeholders' profits and impacts on corporate managers when a risk occurs. The Group's risk management is administered by the Risk Management Committee, established under President and Representative Director, who is the chief risk officer.

# **Risk Management Committee**

The Risk Management Committee consists of 20 members including the President and Representative Director, the Senior Managing Director, Directors, Senior Operating Officers, Operating Officers, and Division Managers. In addition, the full-time Audit and Supervisory Committee Member attends meetings of the committee as an observer. The committee addresses the risks surrounding the Group promptly and appropriately to minimize the loss of stakeholders' interests and impacts on corporate management when a risk occurs while preventing risks.

# Information security

To increase the Company's trustworthiness and competitiveness, the Company has formulated its information security regulations. The regulations consist of basic rules for appropriate use, storage, and operation of information assets that all the officers and employees must comply with in the course of their duties. Based on the regulations, the Company works to secure information security as part of daily management activities, business promotion, and organizational operation.

# Disaster countermeasures

Towa Group takes various measures to prepare for a large-scale disaster.

Specifically, those measures include: (1) provision of emergency supplies, (2) clarification of initial responses and preparation of manuals, and (3) introduction of a safety verification system. In addition, we hold twice-a-year meetings of the Risk Management Committee to share information.





Fire evacuation drill

# Response to the COVID-19 pandemic

The effects of the COVID-19 pandemic are minor within our group. However, should the effects prolong or worsen in the future, closure or shutdown of a particular business facility of our group owing to a cluster of COVID-19 cases identified therein, effects of patients' reluctance to visit hospitals and clinics on sales, and effects of the spread of COVID-19 outside Japan on supply chains for raw materials and APIs might spill over into production.

To address COVID-19, the group implements countermeasures for the following: workstyle (e.g., encouragement of working at home and staggered working hours and encouragement of holding online in-house and external meetings), preventing the spread of COVID-19 (e.g., review of meeting room capacity, installation of acrylic resin panels, and checking for individuals with fever using thermography cameras), and decreasing opportunities of exposure to COVID-19 (e.g., cancelation/postponement of business trips and events in principle). The Group will continue to implement appropriate countermeasures to ensure business continuity.

# **Risk Information**

Towa Group mainly handles prescription products, and among them, generics are our leading products. A generic drug has the same active ingredients, indications, dosage, and administration as a branded drug that has been on the market after its efficacy and safety have been confirmed for a certain period of time. Thus, the Group faces specific risks as a

generic business in addition to risks as a holder of marketing authorization for drugs. After recognizing these risks, the Group makes every effort to avoid their occurrence and set up a system for unexpected events. The Group has been striving to enhance and accumulate corporate strength to endure the impact of such risks.

Control in accordance with the Pharmaceutical and Medical Device Act, etc.

The Group has been manufacturing and marketing prescription products in accordance with the Pharmaceutical and Medical Device Act and related laws and regulations. Any violation of those laws and regulations may cause administrative sanctions by the authorities concerned, which may affect the Group's business activities. To address risks related to regulations, the Group collects information on the laws and regulations to conduct business in accordance with them. In addition, we have developed a company-wide plan and system for compliance promotion.

Patent and re-examination periods

The active ingredients of branded drugs are usually protected by patent rights, and the period is 20 years from the date of application (the period may be extended for up to 5 years). Since generics are approved for marketing after the expiration of the patent period, the extension of the patent period is expected to affect the Group's launch of new

products (new generics).

To address these risks, the Group collects information on patents and re-examination periods as well as facilitates collaboration among related departments. This helps us obtain approval for partial changes such as additional indications as soon as possible after the patent on a branded drug expires. At the same time, the information collected contributes to resolving discrepancies in indications by applying for partial change after the re-examination period.

Re-evaluation based on the Pharmaceutical and **Medical Device Act** 

Re-evaluation of drugs is a system in which the quality, efficacy, and safety of approved drugs are reviewed from the current academic standards. If the drug efficacy re-evaluation shows no usefulness, the product is recalled and disposed of. To address the risk, the Group collects information on scientific and technological progress to appropriately evaluate drugs.

Adverse drug reactions

Generics are released after branded drugs have been used for many years. Their safety information has been confirmed, and they have been re-examined. Therefore, the risk of serious adverse reactions is minimal. However, if they occur, it may affect the Group's financial condition and business performance. To address the risk, the Group collects information on drugs including that on the occurrence of adverse drug reactions in compliance with each country's regulations. This allows us to determine and conduct necessary measures based on the results obtained through assessment and consideration.

**Drug price system and** medical cost containment policy

Owing to the drastic reform of the drug price system, drug prices will be revised every year, beginning in 2021. The Group's financial condition and business performance could be affected if the medical insurance system is reviewed, the drug price system is significantly changed, or the medical cost containment policy is reinforced. To address these risks, the Group aims to sell products at fair prices that match the value of the products while working to reduce cost by increasing production efficiency.

**Patent litigation** 

Since our generic drugs sometimes use API that still has patent rights for their crystal form, formulations, use of the drug, etc., a patent suit may be filed by a manufacturer of new drugs. To address these risks, the Group collects information on patents and facilitates collaboration among related departments, including the development department. This enables us to develop drug formulations that have not been covered by patents held by other companies.

Mark-to-market valuation of derivatives

The Group imports certain semi-finished and raw materials from overseas manufacturers in foreign currencies. To avoid the risk of cost increase due to depreciation of yen and to provide a stable supply of our products, we conduct long-term derivatives transactions. Such transactions are subject to mark-to-market valuation at the time of financial closing, and valuation loss or gain may occur depending on the exchange rate and the interest rate trend in Japan and the US. The Company estimates the future amount of import transactions made in foreign currencies to conduct long-term derivatives transactions within the estimated range. This helps us prevent derivatives transactions from being speculative.

Stagnation and delay of production owing to disasters and other cause: The Group has production sites in Japan (Osaka, Okayama, Yamagata, Shiga, Hyogo, and Shizuoka Prefectures) and Spain (Province of Catalonia), and any of these production sites could be forced to cease business operations owing to the occurrence of natural disasters or technical/regulatory issues to affect the stable supply of products. Besides, if natural disasters and other causes force us to halt purchasing raw materials from some specific supplier(s) and these halted raw materials are challenging to substitute, our business performance could be affected. To mitigate these risks, the Group strives to organize a mutual backup system among our domestic plants and promote multiple sourcing of APIs. Moreover, the Group possesses its own API manufacturing plant to secure a stable supply of APIs.

**Global risks** 

We completed the acquisition of Pensa Investments, S.L. (current trade name, Towa Pharma International Holdings, S.L.; hereinafter, "Towa HD") in 2020. The Group's financial status and business performance could be affected if the acquisition of Towa HD fails to produce the expected effects owing to changes in business environments and business operations of Towa HD, effects of local systems and regulations, likely delay in the progress of the integration process between Towa HD and us, or events unrevealed during due diligence. To address these risks, the Group strives to strengthen a global management structure through the integration process between Towa HD and us.

# **Compliance**

# Compliance policy

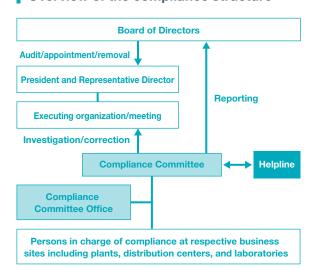
The Company is committed to ethical and law-abiding corporate behavior in accordance with the "Towa Group Code of Conduct." We have established the Compliance Committee to conduct measures to raise compliance awareness of the officers and employees and provide them with training and education for the correct understanding of compliance. Furthermore, we develop and appropriately utilize a whistle-blowing system so as to promptly detect and correct fraudulent acts of the Group's officers and employees.

The Internal Audit Office, which is under the direct supervision of the President and Representative Director, conducts internal audits for all the departments and reports the results directly to the top management. In the case where the Internal Audit Office finds anything that needs improvements, it conducts a follow-up audit to check how the improvements.

# **Compliance structure**

Under the Group's compliance policy, the officers and employees shall promptly report to the Compliance Committee when they find a problem that may cause damage to the Group's business and financial condition. The Compliance Committee is in charge of the whistle-blowing system. It regularly reports the information from the officers and employees of the Group collected through the system to the Board of Directors. The Audit and Supervisory Committee shares information with the Internal Audit Office and the Compliance Committee on a regular basis. It has a right to request report submission.

#### Overview of the compliance structure



# Compliance education

The Company conducts awareness-raising activities for the officers and employees on a daily basis under the leadership of the Compliance Committee. In addition, we set specific periods to promote compliance to take various measures across the Group. Specifically, the top management of the Company conveyed a message to the officers and employees on the importance of compliance. We also conducted a survey to ask the employees of the Group companies in Japan about issues to be addressed regarding their duties and compliance. This not only allowed each employee the opportunity to consider compliance but also allowed the Company to use their answers for measures to be taken in the future.

In addition, we conducted e-learning programs on harassment and whistle-blowing for the officers and employees. Furthermore, we developed a harassment prevention handbook and provided its copies to the Group companies as a measure for the prevention of harassment to respond to the amendment of the Labor Measures Comprehensive Promotion Act. For our subsidiaries overseas, we formulated the code of conduct to comply with laws and regulations, and shared it with those subsidiaries' officers and employees.

Other than the above, we have been delivering easy-tounderstand example cases through our group newsletters.



Group newsletters: What and Why for Compliance

# Whistle-blowing helpline

The Company's whistle-blowing system is used as a helpline shared within the Group companies in Japan. The Compliance Committee appropriately deals with the problems notified through the helpline while protecting whistle-blowers. Together with the monitoring by the Internal Audit Office, the system has contributed to prompt detection and correction of problems. We have also established and started operating whistle-blowing helplines in our subsidiaries overseas.

# **Message from the Outside Directors**



Norikazu Eiki Outside Director (Audit and Supervisory Committee Member)

# An attitude of "people are all that matters, let's be the nail that sticks up" as the starting point for corporate growth

For a company to grow stably over the long term, it is necessary for its organizations to contain a diverse group of people, rather than employees who are just cookie-cutter copies of one another. It has been six years since I took up my post as Outside Director, and during that time I have put my management experience at a pharmaceutical company to provide training for around 140 middle-managers, and during the training sessions, I have exchanged various opinions with them.

One of the Company's standout strengths is the high level of trust and solidarity that its employees feel toward the Company and its management team. But on the flipside of that, I also feel that there aren't many people willing to be the "nail that sticks up" [from the Japanese proverb: "The nail that sticks up will be hammered down."]. In the face of upcoming major changes in the medical and pharmaceutical industries, it will be important for the Company to take on various challenges without fear of failure while respecting the strengths it already possesses.

Through human resource development, I hope that I can continue to play a part in enabling the Company to live up to its vision: We contribute to people's health; We are dedicated to people's genuine smiles.



Kaori Oishi Outside Director (Audit and **Supervisory Committee** Member)

# Leveraging my viewpoint as a lawyer to offer opinions concerning management issues

I have been worked a lawyer for 20 years, dealing with corporate disputes, M&A, and business restructuring. This is my second year as Outside Director of the Company, and the recent scandals in the generics industry have come unexpectedly, shaking confidence with respect to quality and stable product supply. The Company is thus facing a serious management challenge, namely to maintain the trust of the market.

The Company shares information with Outside Directors in a timely and precise manner, with the information covering the management issues it faces and its efforts to enhance corporate value, such as its entry into new health-related businesses. I recognize that it is my role to provide frank opinions from a legal and objective perspective based on the information shared with me.



Kenryo Goto Outside Director (Audit and **Supervisory Committee** Member)

# Genuine smiles and people's health through honest and sound management

The concept of Towa Quality, namely to provide the world with products that rather than just meeting the quality standards required by law, actually offer the levels of quality and added value that are truly needed, and to keep updating the products so that they are the state of the art for the era, is similar to the maxim that informed me during my days at an audit firm to which I belonged: maintaining a sense of ethics that is a step higher than the rest of the world. I am therefore familiar with this sort of serious culture.

Abiding by this concept is not an easy task in the generics industry, which is still waiting to recover its credibility after the quality problems, but one of the things that support this is corporate governance. In accordance with our vision of supporting "genuine smiles" by contributing to people's health, I hope that with my perspective as an outsider, I can help the Company ensure a stable supply of products that can be used with peace of mind not only in Japan but all over the world.

# **Board Members**

#### Itsuro Yoshida

**President and Representative Director** 

May 1979 Joined the Company October 1983 General Manager of Finance & Accounting Department

December 1983 Director / General Manager of Finance & Accounting Department August 1986 Director / General Manager of General Affairs Department

April 1990 Director / General Manager of President Office

Senior Managing Director / General Manager of President Office June 1990 June 1991 Senior Managing Director / Division Manager, Production Division /

General Manager of President Office

Senior Managing Director / General Manager of President Office November 1991 June 1996 President and Representative Director (to present)

October 2003 Chairman and Representative Director of J-DOLPH Co., Ltd. (currently J-DOLPH Pharmaceutical Co., Ltd.) (to present)

October 2010 Chairman and Representative Director of Daichi Kasei Co., Ltd.





November 1998 Joined the Company / Deputy General Manager of Quality

Assurance Department, Yamagata Plant, Production Division

April 2005 General Manager of Quality Assurance Department, Yamagata

Plant. Production Division

April 2007 General Manager of Quality Assurance Department,

Pharmacovigilance & Quality Assurance Division Plant Manager, Osaka Plant, Production Division

October 2009 June 2013 Director / Deputy Division Manager, Production Division

April 2014 Director / Division Manager, Production Division

June 2017 Managing Director / Director in charge of Production Division,

Research & Development Division, Pharmaceutical Research &

Technology Division and API Business Division

April 2019 Managing Director / Director in charge of Pharmacovigilance &

Quality Assurance Division, Production Division and Pharmaceutical Research & Technology Division

Chairman and Representative Director of Greencaps

Pharmaceutical Co., Ltd. (to present)

June 2020 Senior Managing Director of the Company (to present)



# Masao Tanaka

**Directors** 

May 2019

**April 2009** Joined the Company / Deputy-General Manager, Internal Audit Office April 2011 Manager of Internal Audit Office

October 2016 General Manager of Public Relations and Investor Relations Office / General Manager of Human Resources Department

June 2017 Director / Division Manager. Administration Division April 2019 Director / Director in charge of Administration Division

June 2020 Director (to present)

April 2021 Chairman and Representative Director of Protosera Inc. (to present)

#### Toshio Shirakawa

Director (Full-time Audit and Supervisory Committee Member)



October 2006 Joined the Company / General Manager of Development Strategy Department.

Research & Development Division

April 2008 General Manager of Product Portfolio Management Department, Corporate

Planning Division

June 2015 Managing Director / Director in charge of Business Development Office and

International Business Development Department / General Manager of Product

Strategy Management Department

January 2017 Chairman and Representative Director of Greencaps Pharmaceutical Co., Ltd. April 2017 Managing Director / Director in charge of Product Strategy Division, International

Business Division and Development Planning Office of the Company

April 2019 Managing Director

Director (Audit and Supervisory Committee Member) (to present) June 2019

#### Norikazu Eiki

**Outside Director (Audit and Supervisory Committee Member)** 



August 1979 Joined Ciba-Geigy Japan Limited

January 1994 Joined Bayer Yakuhin, Ltd.

March 1997 Director / Plant Manager of Shiga Plant, Bayer Yakuhin, Ltd. July 2002 President and Representative Director, Bayer Yakuhin, Ltd. January 2007 Chairman and Representative Director, Bayer Yakuhin, Ltd.

April 2010 Chairman and Director, Bayer Yakuhin, Ltd.

Outside Director of AnGes MG, Inc. (currently AnGes, Inc.) (to May 2014

present)

Director of the Board, FunPep Co., Ltd. (to present) April 2015

June 2015 Outside Director of the Company

April 2016 Outside Director of Solasia Pharma K.K. (to present) June 2018 Outside Director of the Board, Gene Techno Science Co., Ltd.

(to present)

June 2019 Outside Director (Audit and Supervisory Committee Member)

of the Company (to present)

#### Kaori Oishi

**Outside Director (Audit and Supervisory Committee Member)** 

October 2001 Registered as an attorney at law

October 2001 Joined Kitahama Law Office (currently Kitahama Partners)

January 2013 Partner of Kitahama Partners (to present)

Outside Director of PALTAC CORPORATION (to present) June 2017 June 2020 Outside Director (Audit and Supervisory Committee Member)

of the Company (to present)

# Kenryo Goto

Outside Director (Audit and **Supervisory Committee Member)** 



September 1981 Joined Asahi & Co. (currently KPMG AZSA LLC)

March 1984 Registered as a certified public accountant

May 2005 Partner of KPMG AZSA & Co. (currently KPMG AZSA LLC) July 2010 Board member, Head of Division 3, Osaka Office, KPMG AZSA LLC

July 2013 Senior Executive Board member of KPMG AZSA LLC July 2015 Osaka Office Managing Partner of KPMG AZSA LLC

Representative of Kenryo Goto Certified Public Accountant Office (to present) July 2020 June 2021 Outside Director (Audit and Supervisory Committee Member) of

the Company (to present)



#### Basic approach

To fulfill our responsibilities as a company providing ethical drugs, the Company strives to provide information to patients and healthcare professionals in many different ways, which include providing and collecting pharmaceutical information through our medical representatives. We also focus on our responsible business activities ranging from stable supply to quality assurance.

#### **Responsible Business Activities**

# **Information Provision by Medical Representatives**

Our medical representatives, whose number is proudly reported to be the largest among the domestic manufacturers of generics, work on the provision, collection, and transmission of pharmaceutical information. We are also enhancing the network of medical representatives to be able to respond to various needs of diverse medical service providers, including clinics, local flagship hospitals, and health insurance pharmacies. Further, we provide a qualification system for medical representatives to recognize and enhance their specialized capabilities in cancer, immunology, CNS areas, etc., so that we can provide information requiring more specialized expertise.

# **Information Provision by DI Center**

To ensure expeditious and accurate information provision, the Company integrated multiple contacts into Drug Information (DI) Center of Drug Information Department, and use the call-center system connected to customer information. This allows us to promote optimal information provision activities for proper uses of generics. We also offer contact offices to receive inquiries even at night or on holidays on a 24-7 basis.

Customer Service is offered for patients and the general public. Toll-free services are available for various pharmaceutical inquiries about combinations of multiple medications, side-effects, etc.

### **Information Provision via Websites**

We provide necessary information about our ethical drugs through the corporate site and the site for medical professionals. The corporate site offers information about generics and materials that can be used by parents trying to help children take medication, as well as other useful tips. The site for medical professionals provides product information, governmental actions on medical practices, and materials that can be used for medical instructions for patients.

# **Information Provision to Promote** the Correct Uses of Medicines

To promote the correct uses of medicines, we provide various explanatory materials for patients, e.g., about how to take medicines, and conduct studies, e.g., on combinations of medicines and other food/beverages other than water to alleviate the bitterness for family caregivers trying to help their children or those they are caring for to take medication. The materials and results of these studies are provided to patients and their family members through medical institutions.

People can access information about medicines by

scanning a QR code\* printed on a product package with their smartphone or cell phone. For formulations for children, QR codes provide information to parents about the taste of medication and how to help patients (their children) take medication smoothly.

\* QR code is a registered trademark of DENSO WAVE INCORPORATED.

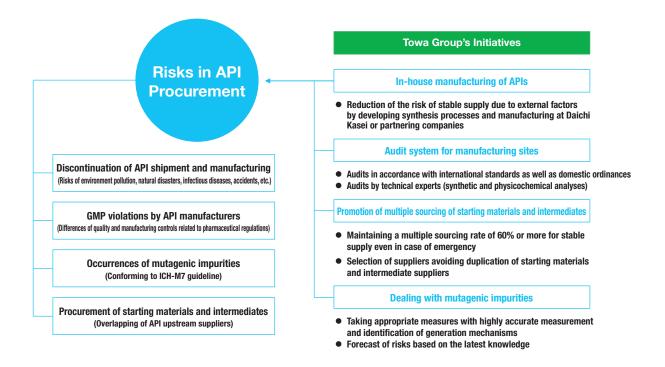


Booklet to provide information

# Stable Supply System

Stable supply is one of our important missions to be accomplished as an ethical drug manufacturer. We produce products in our three plants in Osaka, Okayama, and Yamagata under a two-shift operation system in case any plant shuts down due to a natural disaster, etc. A backup system of the three plants is being constructed in preparation for an emergency in any one plant, so that the other two plants can adopt a three-shift system.

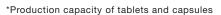
Products dispatched from the plants are stored in the East Japan Distribution Center (in Yamagata) and West Japan Distribution Center (in Okayama). This enables us to deliver our products nationwide from either of the distribution centers in case one of which is shut down due to a natural disaster, etc. We realize stable supply through the two distribution centers in East and West Japan.

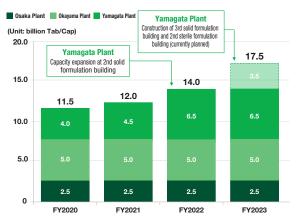


# **Production System**

We currently have a production system capable of annual generics production of 11.5 billion tablets\* at the three plants. To respond to a further increase in demand, we plan to increase production volume to 14.0 billion tablets by the end of FY2022, build the 3rd solid formulation building in Yamagata Plant by the end of FY2023, and achieve the production capacity of 17.5 billion tablets from FY2024 onward.

To ensure stable product supply, production of oral dosage forms is dispersed to the three plants; and the production of injections is integrated into Yamagata Plant built with the seismically isolated structures to minimize natural disaster risks. The three plants take pride in the advanced facilities to ensure high quality and stable supplies, supporting our confidence in the future.





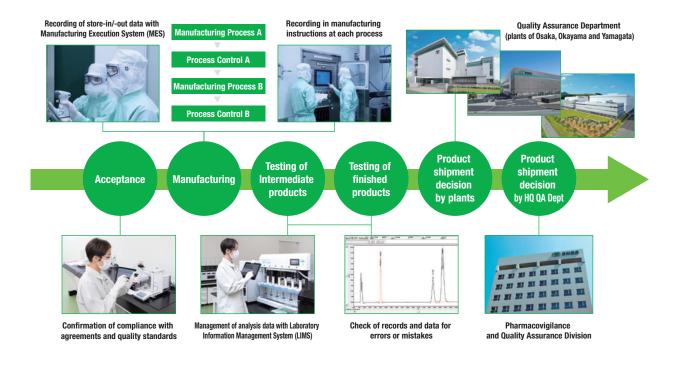
Targeting production capacity of 17.5 billion tablets/capsules per year by the end of FY2023

# **Quality Assurance System**

Strict quality control standards established by the national government apply to all processes of ethical drug manufacturing operations. In order to be a trustworthy company, we carry out company-wide quality control initiatives ranging from product R&D, manufacturing, marketing, and after-sale operations, and establish the quality assurance system required for ethical drugs.

In the 5th Mid-term Business Plan. Policy 1 is "Enhancing generics business as a core." Under the policy, one of the key themes is further

strengthening the quality assurance system in order to be a more trusted and needed company as a comprehensive generics manufacturer. Under the quality assurance system, we not only comply with relevant regulations including the Good Manufacturing Practice (GMP) Ministerial Ordinance, but also strive to assure the quality and safety of pharmaceutical products through introducing international standards and establishing our original system and training programs from the perspective of "minimizing human error," one of the GMP three principles.



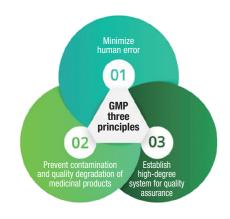
# **GMP Three Principles**

Pharmaceuticals production is based on Good Manufacturing Practice (GMP), the standards for manufacturing control and quality control for drugs laid down by the nation.

The following three principles are stipulated in the GMP:

- (1) minimizing human error,
- (2) preventing contamination and quality degradation of medicinal products, and
- (3) establishing high-degree system for quality assurance.

The Company has put in place procedures compliant with the GMP three principles in all of our plants in Yamagata, Osaka, and Okayama, and strives to manufacture reliable-quality pharmaceuticals always required at a higher level.



#### Making job satisfaction and fostering talented human resources



# **Career Development Support**

Under the belief that talented human resources are the foundation of a trusted company, we work to make job satisfaction, foster talented human resources, and strengthen our organization. Accordingly, one of the policies in the 5th Mid-term Business Plan is "Making Job Satisfaction and Fostering Talented Human Resources." To this end, we started "Towa work style reforms" in October 2020.

As one of the work style reforms, we put more effort into helping each employee develop their career path. Starting from April 2021, the Human

Resources Division staff have career development meetings with employees to enhance more personalized support. Going forward, we will encourage employees to understand the importance and necessity of developing their career paths and support them in developing their mid- to longterm career vision. To help employees achieve their career visions, we will aim to become a company that encourages employees to grow in a proactive and planned manner.

# **Our Commitments (T-SMILE)**

We have established a new course of action named T-SMILE. This is our philosophy created when we marked the 70th anniversary of our foundation to accommodate our growth and increasing employees and further disseminate our vision to employees.

T-SMILE is an acronym of six words: Truthful that means sincerity, honesty and fairness; Speed that represents swift decision-making, action and information sharing; Mission that expresses missions and passion to be of service to help people maintain their good health in communities around the world; Idea that represents creativity and imagination to challenge for unprecedented transformation; Linkage that gives the impressions of connections between people and information, coexistence, and co-prosperity; and Excellence that represents the mind to choose the most appropriate technologies that fit with the times and highest quality. These words serve as a course of action and criteria based on which employees help realize the Group's vision "We contribute to people's health" and "We are dedicated to people's genuine smiles" through corporate activities.



# **Medical Representatives**

The Company places priority on developing medical representatives (MRs) and strengthening their organization, and strives to foster talented human resources. In accordance with the MR Education Training Guidelines, we develop our original education programs and provide ongoing training, which covers expert knowledge about products, high ethical standards required for MRs handling liferelated products, and skills in explaining products and communication. In this way, we aim to develop highly qualified medical representatives who can gain the trust of healthcare professionals.



# **Original Qualification Systems**

From the perspective of ensuring reliable quality and safety, we develop employees with high awareness through our educational training programs and original qualification system. Specific examples include an MR qualification specialized in cancer, a GMP auditor certification, and an expert certification system. The expert certification system is a system whereby we certify our employees who have a higher degree of technical skills and greater knowledge in manufacturing, packaging, testing, and quality assurance units. By promoting these certification systems, we help employees in each area develop into specialists in manufacturing control and quality control. Meanwhile, we aim to develop employees who are highly aware of ensuring quality and safety.



# **Health and Productivity Management**

We promote health and productivity management and have an organization responsible for company-wide safety and health management. We perform various activities for creating a worker-friendly environment, promoting employees' mental health, and enhancing employees' health.

In March 2021, we were recognized as one of the Certified Health and Productivity Management Outstanding Organizations for four consecutive years. We will continue to perform various activities for promoting employees' and their family members' health.

# **Our Efforts for Diverse Work Styles**

We perform various activities to help employees who raise their children or take care of their family members in need of nursing care. In 2010, we were awarded the next-generation certification mark called Kurumin. The logo features a swaddled baby. The Ministry of Health, Labour and Welfare grants the certification logo if it certifies companies as childrearing-friendly businesses.

We have various parental and nursing care systems for our employees. For example, they can take parental leave until their children turn three years old for the maximum length, they can extend using the shorter working hour system for parenting until their children finish the sixth grade at elementary school, and we provide family support leave to which employees are entitled when they need to take care of their sick family members requiring nursing care.

I was able to take satisfying parental leave thanks to cooperation by people around me

#### Shuhei Yamamoto

Deputy General Manager, Purchasing Planning Department, Purchasing Division

When my wife gave birth to our third child, I took parental leave of four weeks to help reduce my wife's burden because our first and second children are twins still at age of four. I started consulting with my boss and co-workers and made preparations four months before taking parental leave. My boss, team members and other employees around me were cooperative, so I smoothly handed over my work. During parental leave, I struggled with raising our children at first, but when I got used to it, I was able to do it naturally. I feel that it was worth taking parental leave because during the four-week period, I was given an irreplaceable opportunity of spending time with our newborn and I was able to support my wife having a hard time after childbirth. I hope that more employees are aware of parental leave and that childrearing employees can have more options.

#### **Social Contribution Activities**

# Company-sponsored **Daycare Centers**





Company-sponsored daycare centers are childcare facilities established by companies to provide their employees with flexible childcare services according to the employees' different ways of working. We established our company-sponsored daycare centers near Okayama and Yamagata Plants in 2018 to realize a work environment where childrearing employees can work for the Company without any concerns and to contribute to local communities by reducing the number of children on waiting lists at daycare centers. We also conclude joint use contracts for company-sponsored daycare centers of other companies to provide additional options. In this way, we are committed to creating an environment where employees find it easier to be reinstated after parental leave.

#### On-demand Lectures







We deliver on-demand lectures using our technical skills and content for children through an event called "After-school Educational Program for Kids" held in elementary school districts of Osaka Prefecture so that children can have an enriching learning experience. We so far delivered lectures including the one themed "Let's do an experiment and explore the secrets of medicine! - Generics are full of ingenious ideas - "

# **High School Student Business** Contest

We held a "High School Student Business Contest for the Future and People's Health" for the second time in FY2020. As a part of our efforts to widely disseminate the Group's vision "We contribute to people's health" and contribute to a wide variety of health-related industries, the contest is aimed at seeking fresh ideas

from high school students who will lead the future of Japan and creating a social contribution opportunity for them.



# **Introduction of Music Therapy Videos**

In January 2021, we released music therapy videos titled "Music and Mind-For Everyone's Smiles-" on our homepage. Music therapy is psychotherapy using the nature of music and one of the nonpharmacological therapies for diseases including developmental disabilities, dementia, and mental illness. We released

the videos as part of our efforts to provide useful information to help people prevent disease and maintain their good health.



# **Well-care Exercise Programs**

We released a website called "Well-care Exercise Programs" on our homepage to introduce exercise programs, which are designed to support people's mental health. The website introduces several exercise programs with different intensity levels developed under the supervision of the Japanese Association of Sports Psychiatry

with the slogan "Anybody can easily enjoy at anytime and anywhere," allowing people to do exercise according to their physical strength.





#### **Basic approach**

We act based on the principles in "The Charter of Corporate Behaviors in Towa Group" with high ethical standards and social good sense to promote proper corporate activities enabling us to gain trust and support from society. In our action, we strive to reduce global environmental load as part of our social responsibility as a good corporate citizen.

Concretely, we are dedicated not only to proper management of chemical substances and prevention of pollution, but also to actions for alleviating environmental concerns through plant drainage and emission systems and taking energy-saving and decarbonization measures through effective uses of mega solar systems. Furthermore, we are aggressively working to achieve an eco-friendly manufacturing method of APIs.

# Reducing CO<sub>2</sub> through warm water generation by using waste heat from large refrigerators

Dehumidification with cold water is essential for controlling air conditions in clean rooms. Yamagata Plant has introduced a double-bundled centrifugal refrigerator, a type of large chiller to produce cold water. This equipment can generate warm water by collecting and using heat that is normally discarded. This enables us to reduce CO<sub>2</sub> emissions by about 24% compared to the conventional method of generating warm water using steam from boilers.



Double-bundled centrifugal refrigerator

# Installing photovoltaic power generation facilities covering about 1,000 households

West Japan Distribution Center in Okayama Prefecture has installed photovoltaic power generation facilities on the roofs of the facilities and produced electricity since 2012. In 2014, the Center added another photovoltaic installation with generating capacity of up to 1.5 MW using idle land on its premises. Together, the Center is now able to generate about 3.16 million kilowatts of electricity annually. This is about 1,000 households worth of electricity demand.



Photovoltaic power generation facilities in the West Japan Distribution Center

# Realizing an eco-friendly manufacturing method of APIs

New Energy and Industrial Technology Development Organization (NEDO) selected our initiative to manufacture APIs eco-friendly as a publicly solicited subcontractor for the Development of Continuous Production and Process Technologies of Fine Chemicals. As an eco-friendly manufacturing method, this is aiming to develop the flow precision synthesis for producing fine chemicals as part of NEDO's Feasibility Study Program on Energy and New Environmental Technology. We are pursuing an eco-friendly, green and sustainable chemistry by replacing the batch method generating large quantities of waste and CO2 emissions with the manufacturing process with the continuous flow method using energy-saving catalytic reactions with low waste emissions as the key.

# **11-Year Financial Summary**

	2011	2012	2013	2014
Net sales (JPY million)	46,145	48,719	55,241	61,351
Operating profit (JPY million)	9,654	9,107	7,723	7,706
Ordinary profit (JPY million)	9,396	9,841	9,544	8,834
Profit attributable to owners of parent (JPY million)	5,846	5,737	6,201	5,992
Comprehensive income (JPY million)	5,791	5,745	6,348	5,999
Net assets (JPY million)	46,664	50,494	55,610	60,147
Total assets (JPY million)	72,964	81,244	89,705	103,318
Net assets per share (JPY)	906.08	990.36	1,090.70	1,179.69
Earnings per share (JPY)	113.53	111.49	121.62	117.54
Diluted earnings per share (JPY)	_	_	_	_
Equity ratio (%)	64.0	62.2	62.0	58.2
ROE (Return on equity) (%)	13.2	11.8	11.7	10.4
Price-earnings ratio (%)	12.35	12.26	13.68	12.63
Cash flows from operating activities (JPY million)	5,739	3,379	8,645	8,144
Cash flows from investing activities (JPY million)	(7,854)	(8,482)	(11,298)	(11,300)
Cash flows from financing activities (JPY million)	4,220	879	2,793	3,529
Cash and cash equivalents at end of year (JPY million)	8,031	3,798	3,985	4,675
Number of employees	1,454	1,567	1,696	1,879
R&D expenditure (JPY million)	3,260	4,076	4,478	5,296
Capital investment (JPY million)	9,234	11,251	7,855	9,727
Depreciation (JPY million)	1,873	2,637	4,909	5,407
Dividend per share (JPY)	65.0	75.0	75.0	75.0
Dividend payout ratio (%)	19.1	22.4	20.6	21.3

Note: The Company conducted a 3-for-1 stock split of common shares effective April 1, 2019.

We calculated net assets per share and earnings per share assuming that the said stock split was conducted at the beginning of the fiscal year ended March 31, 2011.

2015	2016	2017	2018	2019	2020	<b>2021</b> (FYE March
71,470	82,115	84,949	93,430	105,104	110,384	154,900
11,105	11,134	6,869	11,643	15,968	16,143	19,923
15,437	10,157	7,417	11,717	18,865	20,990	18,677
11,118	7,684	5,576	6,495	13,475	14,503	13,958
11,175	7,313	5,858	6,533	13,409	14,948	14,469
70,048	70,605	74,945	79,920	91,771	104,665	116,599
121,187	156,851	165,247	177,181	188,803	230,016	245,668
1,373.89	1,434.79	1,522.99	1,624.09	1,864.92	2,126.72	2,369.21
218.07	154.19	113.32	132.00	273.85	294.74	283.62
_	436.29	314.23	122.03	253.32	272.62	271.93
57.8	45.0	45.4	45.1	48.6	45.5	47.5
17.1	10.9	7.7	8.4	15.7	14.8	12.6
10.50	9.98	16.56	16.79	10.64	7.69	8.61
8,037	3,732	10,195	19,230	19,002	19,164	12,008
(8,230)	(19,032)	(22,206)	(20,093)	(3,994)	(39,541)	(9,100)
238	27,970	(92)	4,670	(809)	11,748	184
5,208	18,526	7,112	11,511	26,652	18,713	22,915
2,060	2,203	2,408	2,449	2,472	3,325	3,456
6,144	8,924	9,352	7,725	7,916	8,566	10,642
13,816	15,792	25,026	12,166	6,011	6,236	10,353
5,724	7,329	7,980	8,173	8,340	8,285	9,674
95.0	95.0	95.0	95.0	107.5	44.0	44.0
14.5	20.5	27.9	24.0	13.1	14.9	15.5

# **Management Discussion and Analysis of Financial** Position, Operating Results, and Cash Flows

The details of the financial reports are excerpts from Annual Securities Report (from April 1, 2020 to March 31, 2021).

#### Overview of Performance

#### [1] Business environment

In the consolidated fiscal year ended March 31, 2021, the Japanese economy remained in a severe situation due to the COVID-19 pandemic. After lifting the state of emergency in May last year, the level of social and economic activities was gradually raised. Under such circumstances, we saw signs of a recovery from the extremely difficult situation. However, the outlook for the situation remains uncertain, as the number of cases of the COVID-19 has been increasing again, and some areas have reinstated the state of emergency. During the period, starting vaccination brought recovery from the economic slowdown caused by the spread of the COVID-19 around the world and the blockade of cities. However, risks such as the future resurgence of infection remain.

In the generics industry, the Cabinet decided the "Basic Policy on Economic and Fiscal Management and Reform 2017" in June 2017. It stated that the volume share of generics would reach 80% by September 2020, and that the Cabinet would consider further measures to promote the use of generics to achieve this target as soon as possible. As a result of this decision, the Japanese government has implemented various measures since the revision of medical fees in April 2018. Furthermore, in revising medical fees in April 2020, the government decided "Further Promotion of Generic Medicine and Biosimilars Use" policy, and generics have become more popular. Consequently, the volume share in December 2020 reached 79.4%, which almost achieved the target (according to the survey by Japan Generic Medicines Association in October-December 2020).

On the other hand, the government revised drug prices in October 2019 and April 2020. Also, it revised them in April 2021 based on the "Basic Policy on Economic and Fiscal Management and Reform 2020" approved by the Cabinet in July 2020. As described above, the government will revise the drug prices every year, beginning in 2021. The government decided a policy to revise the drug prices in intermediate years in addition to the regular revisions once every two years. Therefore, we expect that extremely tough conditions for the pharmaceutical industry will continue.

We announced the 4th Mid-term Business Plan 2018-2020 PROACTIVE in May 2018 against this backdrop of such dramatic changes in the environment surrounding the industry. Based on the plan, we took on challenges such as entering new markets and creating new businesses as well as maintaining the foundation of the domestic generics business to become a company needed by society and local communities at any time.

#### [2] Initiatives for sales growth

Last June, we launched new products including 22 items of 10 APIs with a sales plan of JPY 3,200 million for the first year. In December, we began selling another 10 items of two APIs with the plan of JPY 770 million for the first year. In addition, the number of our generics has reached 770 items of 343 APIs as a result of selling new drugs to improve the quality of life.

#### [3] Initiatives for entering overseas markets

As part of entering new markets, we acquired Pensa Investments, S.L. (Headquarters location, Catalonia, Spain; current trade name, Towa Pharma International Holdings, S.L.; hereinafter, "Towa HD") in the preceding period, and achieved business expansion in the European and U.S. markets. Going forward, we aim to further expand our business by utilizing Towa HD's sales network in several European countries and the United States as well as the production bases in Europe compliant to European and the United States standards.

#### [4] Creation of new businesses

With the hope of becoming a company needed by society and local communities at all times, we are researching and commercializing new health related businesses, centering on extension of healthy life expectancy; maintenance of healthy conditions; restoration of health at pre-symptomatic stage; and response to the local comprehensive community care system. As part of these efforts, we began a joint research project in April 2020 with National Cerebral and Cardiovascular Center to establish medical evidence for the efficacy of taxifolin, a plant-derived ingredient, in preventing dementia. We also signed a joint research contract with Osaka Psychiatric Medical Center on biomarkers for Alzheimer's dementia. Besides, we acquired shares of Protosera Inc. through third-party allotment in March 2021 to launch a testing service business. Protosera has been certified as a sanitation testing laboratory and is engaged in disease risk testing services using its proprietary basic technology for protein analysis.

Additionally, we established an organization to plan and implement marketing strategies for new businesses, support frontline sales staff and promote activities, and work to strengthen our sales capabilities. In the previous year, we started selling "comuoon," an interactive assistive device to convert the voice of speakers into sound that is easy to hear, offered by Universal Sound Design Inc. Sales of "comuoon" also developed well.

#### [5] Operating results

For the consolidated fiscal year under review, the Group recorded net sales of JPY 154,900 million (up 40.3% YoY). While the COGS ratio was 57.7%, up 3.6 percent points YoY, gross profit was JPY 65,451 million (up 29.2% YoY). SGA expenses was JPY 45,527 million (up 32.0% YoY). Consequently, operating income was JPY 19,923 million (up 23.4% YoY), but ordinary income was JPY 18,677 million (down 11.0%) due to the recording of loss on valuation of

derivatives, and profit attributable to owners of parent was JPY 13,958 million (down 3.8% YoY).

Domestic net sales were JPY 118,685 million (up 7.5% YoY), reflecting steady sales of recently launched products, despite the effects of NHI price revisions in October 2019 and April 2020 and some impacts of the spread of COVID-19. The COGS ratio improved 0.5 percent points YoY to 53.6%, and gross profit was JPY 55,109 million (up

8.8% YoY). SGA expenses was JPY 35,612 million (up 3.2% YoY) due to increases in personnel and R&D costs. Consequently, operating income came in at JPY 19,497 million (up 20.8% YoY).

Overseas net sales were JPY 36,214 million, COGS ratio was 71.4%, and gross profit was JPY 10,341 million. SGA expenses amounted to JPY 9,915 million. Consequently, operating income was JPY 425 million.

# Financial position

The financial condition for the consolidated fiscal year under review is as follows.

#### [1] Assets

Total assets at the end of the consolidated fiscal year under review amounted to JPY 245,668 million, up JPY 15,651 million YoY. This was mainly due to an increase in inventories of JPY 9,902 million, an increase in cash and deposits of JPY 4,201 million, and an increase in trade notes and accounts receivable of JPY 2,930 million, despite a decrease of JPY 3,811 million in investments and other assets.

#### [2] Liabilities

Liabilities amounted to JPY 129,069 million, up JPY 3,717 million YoY. This was mainly due to an increase in long-term debt of JPY 33,305 million, despite decreases in short-term debt of JPY 20,257 million and convertible bond of JPY 10.870 million.

#### [3] Net assets

Net assets amounted to JPY 116,599 million, up JPY 11,934 million YoY. This was mainly due to an increase in retained earnings of JPY 11,458 million. Consequently, capital-to-asset ratio was 47.5% at the end of the consolidated fiscal year under review.

\*We had applied a provisional accounting treatment for the business combination with Towa HD in the previous consolidated fiscal year. However, since it was finalized in the consolidated fiscal year under review, the amounts reflecting the provisional accounting treatment are used in the comparison and analysis with the previous consolidated fiscal year.

# Cash flows

Cash and cash equivalents at the end of the consolidated fiscal year under review amounted to JPY 22,915 million, up JPY 4,201 million YoY. Each cash flow for the consolidated fiscal year under review and factors behind it are as follows:

#### [1] Net cash provided by (used in) operating activities

Net cash provided by operating activities amounted to JPY 12,008 million (down JPY 7,155 million in the inflow YoY). This was mainly due to profit before income taxes of JPY 18,728 million (down JPY 1,981 million YoY), partially offset by an increase in inventories of JPY 9,707 million (up JPY 5,406 million YoY).

#### [2] Net cash provided by (used in) investing activities

Net cash used in investing activities was JPY 9,100 million (down JPY 30,441 million in the outflow YoY). This was mainly attributable to purchase of property, plant and equipment of JPY 9,137 million (up JPY 4,588 million YoY).

#### [3] Net cash provided by (used in) financing activities

Net cash provided by financing activities amounted to JPY 184 million (down JPY 11,564 million in the inflow YoY). This was mainly due to a net decrease in short-term debt of JPY 20,251 million (net increase of JPY 20,200 million in the previous consolidated fiscal year), repayments of longterm borrowings of JPY 6,895 million (up JPY 499 million YoY), and payments for redemption of bonds with share acquisition rights of JPY 10,850 million yen (up JPY 10,850 million YoY), partially offset by proceeds from long-term borrowings of JPY 40,500 million (up JPY 40,500 million YoY).

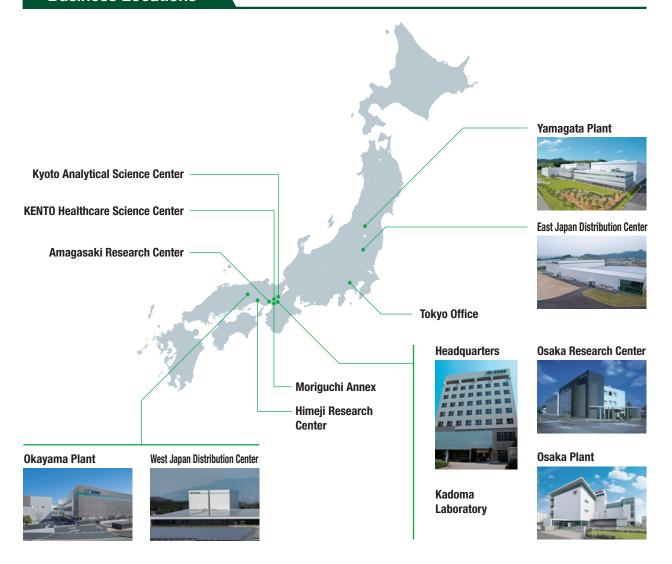
# Dividend policy

We have a basic policy of paying dividends continuously and steadily in accordance with our performance, while enhancing internal reserves to prepare for future business development, such as strengthening research and development capabilities and securing capital expenditure funds.

Based on this policy, we paid a dividend of JPY 44 per share for the current fiscal year (including an interim dividend of JPY 22 per share and a year-end dividend of JPY 22 per share). Our basic policy is to pay dividends of surplus twice a year for the interim dividend and the yearend dividend. The decision-making bodies for these dividends of surplus are the General Meeting of Shareholders for the year-end dividend and the Board of Directors for the interim dividend.

We have stipulated in the Articles of Incorporation that the Company, by resolution of the Board of Directors, may pay an interim dividend as of September 30 of each year, which is set to be the record date for the interim dividend.

#### **Business Locations**



# **Major Group Companies**



#### **J-DOLPH Pharmaceutical** Co., Ltd.

Manufacturing and selling of ethical

Headquarters: Koka, Shiga



#### Daichi Kasei Co., Ltd.

R&D and manufacturing of APIs and

Headquarters: Fukusaki, Kanzaki, Hyogo



#### **Greencaps Pharmaceutical** Co. Ltd.

Producing soft capsules for pharmaceutical products.

Headquarters: Fujinomiya, Shizuoka



#### **Towa Pharma International** Holdings, S.L.

Manufacturing and selling of ethical and OTC drugs

Headquarters: Barcelona, Spain

#### Non-consolidated subsidiaries

#### T Square Solutions Co., Ltd.

Providing healthcare related IT services Headquarters: Moriguchi, Osaka

## Protosera Inc.

Disease risk testing service business and research and development of diagnostic drugs Headquarters: Osaka, Osaka

#### **Company Outline**

As of March 31, 2021

#### **Overview of Company**

Company name TOWA PHARMACEUTICAL CO., LTD.

2-11, Shinbashi-cho, Kadoma-shi, Osaka 571-8580 **Headquarters** 

Main phone: +81(0)6-6900-9100

Representative President and Representative Director Itsuro YOSHIDA

**Established** June 1951 Incorporated April 1957

Listina The first section of the Tokyo Stock Exchange (TSE)

(Securities code :4553)

JPY 4,717.70 million Capital stock

Business operations Manufacturing and selling of ethical drugs

#### **Business locations and sales outlets**

**Headquarters** Headquarters Moriguchi Annex Tokyo Office

Research & Osaka Research Center Development Kadoma Laboratory

Laboratories **Kyoto Analytical Science Center** 

KENTO Healthcare Science Center Amagasaki Research Center Himeji Research Center

**Plants** Osaka Plant Okayama Plant Yamagata Plant

Distribution West Japan Distribution Center centers East Japan Distribution Center

Sales offices 71 sales offices and sales sites 60 sites of agents

#### **Consolidated subsidiaries**

J-DOLPH Pharmaceutical Co., Ltd.

Daichi Kasei Co., Ltd.

Greencaps Pharmaceutical Co. Ltd.

Towa Pharma International Holdings, S.L. and seven companies

#### Stock Data

As of March 31, 2021

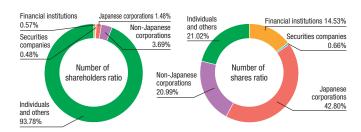
Shares authorized ·····	147,000,000 shares
Shares issued ·····	51,516,000 shares
Number of shares constituting one unit ·····	100 shares
Number of shareholders	5,819 shareholders

### Major shareholders (Top 10)

Shareholder name	Number of shares (Thousand)	Ownership (%)
Yoshida Office Co., Ltd.	20,100	40.84
The Master Trust Bank of Japan, Ltd. (Trust Account)	2,201	4.47
Itsuro YOSHIDA	1,455	2.95
BNYM AS AGT/CLTS 10 PERCENT	1,445	2.93
TOWA PHARMACEUTICAL Kyoeikai	1,440	2.92
Custody Bank of Japan, Ltd. (Trust Account)	1,213	2.46
TOWA PHARMACEUTICAL Employee Stock Ownership Group	890	1.80
State Street Bank and Trust Company	726	1.47
Yoshida Estate Ltd.	648	1.31
The Bank of New York Mellon Corporation	516	1.05

Note: The Company holds 2,301,475 shares of treasury stock but is excluded from the above major shareholders. The Company calculated the ownership by deducting the number of treasury shares.

# Share breakdown by shareholder type



## Stock price



