

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.

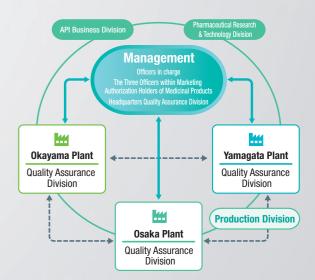
Furthermore, in addition to the general education and training, we have introduced an original qualification system to recognize those with higher skills and knowledge in departments such as manufacturing, packages, testing, and quality assurance, as an "expert." Our system ensures that specialists in 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



Feature Topic 2 Developing overseas market

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 guality 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

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.

in Europe and the United States, knowledge in the

been our long-standing issue in advancing overseas,

knowledge in business practice in different regions, and

production facilities that have experience of exporting

standards of competent authorities in Europe and the

manufacturing approval process in each country which had

products to other countries and are in compliance with the

United States such as European Medical Agency (EMA) and

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





Pensa Pharma, S.A. 🔳 💽 📲 📕

Generics sales company in Europe

Headquartered in Barcelona, Catalonia, Spain, Pensa Pharma, S.A. engages in sales of generics mainly in the European market through its five bases in Europe.

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.

TOWA

Established: 1983

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."

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.

* The figure includes no double counting between Europe and the United States.

Headquarters location: Catalonia, Spain Established: 2006 Business: Generics business mainly in Europe Number of employees: Approximately 180 Business bases: Five in Europe

Headquarters location: Connecticut, United States

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





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 m² Products manufactured: Pellets capsules tablets liquid formulations, and others

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Financial Highlights



Non-Financial Highlights



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.

Energy usage





* Three Towa plants

(%) 60-

* Per sales of JPY 1 million (non-consolidated)



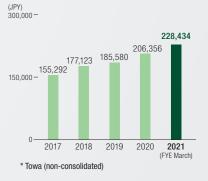




2017 2018 2019 2020 **2021** (FYE March) * Towa (non-consolidated)

Medical expense reduced





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 guickly 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 "comucon," 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 futureoriented 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.

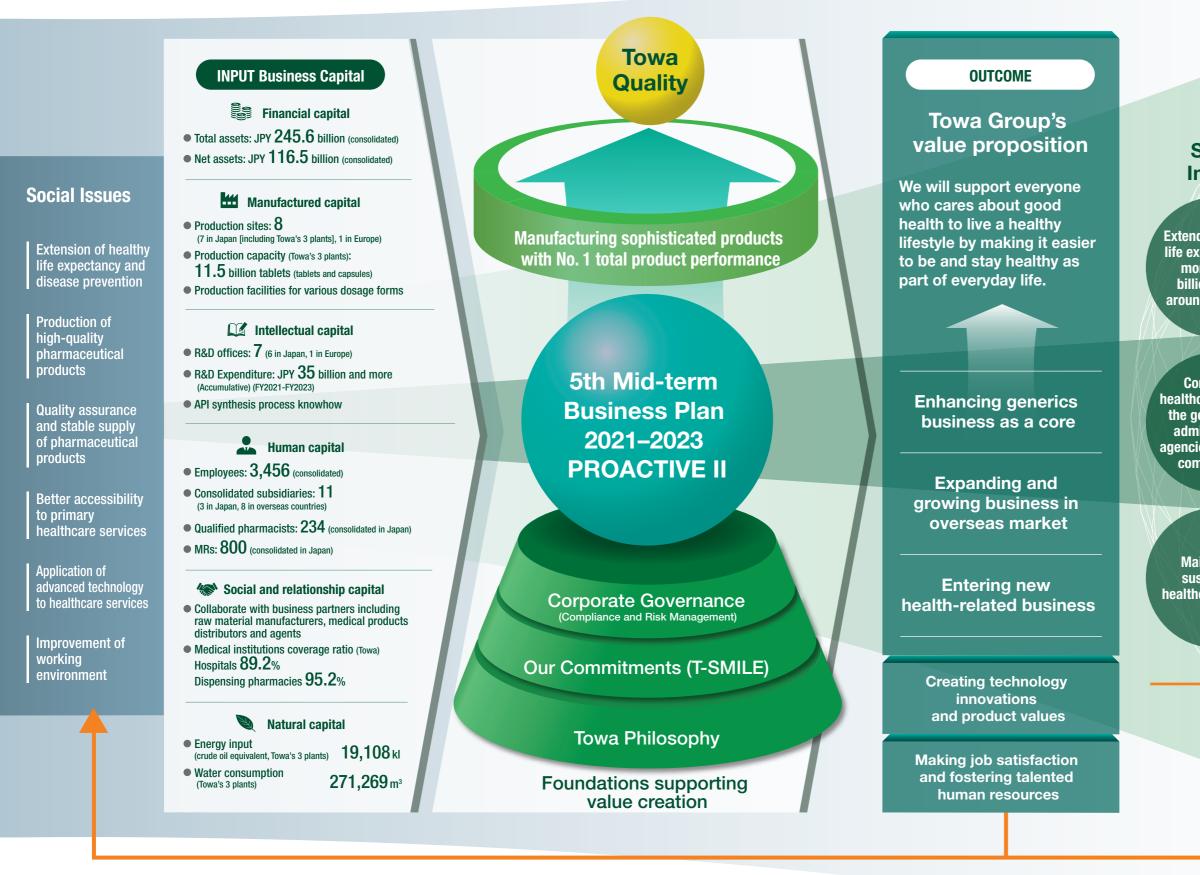
Our priority is to be a company that can continue to provide value to all the people connected with the Towa Group.

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."



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 quarter 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.

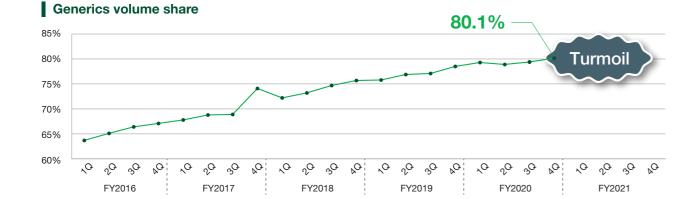
There is a pressing need of industry-wide initiative to restore confidence in generics which has been eroded

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.



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.

Intellectual capital

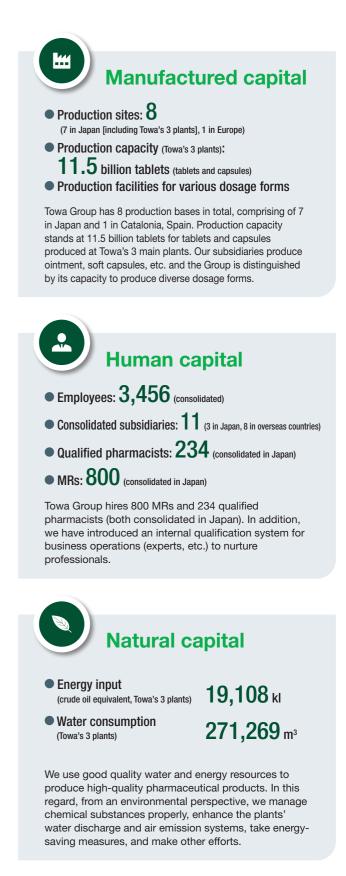
- Research hubs: 7 (6 in Japan, 1 in Europe)
- R&D Expenditure: JPY 35 billion and more (Accumulative) (FY2021–FY2023)
- API synthesis process knowhow

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.

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.



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 (3) Entry to new markets and creation of new businesses

Basic Policy (1) Steady growth of of stable domestic generic business supply

Basic Policy (2) Further evolution of product quality for sustainable growth

Basic Policy (1)

Steady growth of domestic generic business / continuation of stable supply

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.

We expanded generics business in Japan by newly launching 76 items of 30 APIs during the three years to

a start in selling biosimilar products. Furthermore, we expanded manufacturing facilities to ensure the

at the three plants in Osaka, Okayama, and Yamagata. *Production capacity of tablets and capsules

FY2020. In addition, we concluded a joint sales agreement with Celltrion Healthcare Japan Co., Ltd., and made

continuation of stable supply, and have achieved a production capacity target of 11.5 billion tablets* per year

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

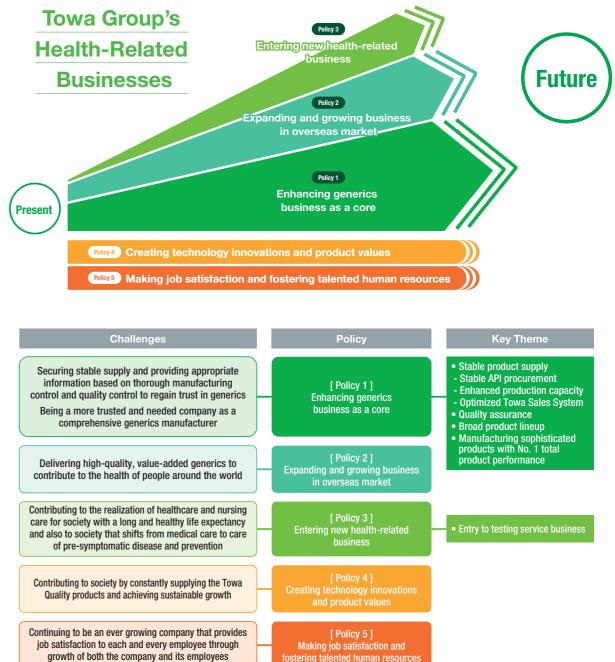
	Net sales	Operating income (accumulative)	Capital-to-asset ratio	R&D expenditure (accumulative)	Capital investment (accumulative)	Dividend policy
Targets	JPY 100.0 billion or more	Initial target of JPY 30.0 billion or more ▼ From May 2019 Modified target JPY 40.0 billion or more	50% or higher Improvement of financial stability	JPY 26.0 billion or more Product development plan aiming for stable launches Improvement of products in response to requests from healthcare professionals and patients	JPY 20.0 billion or more Capital investment for maintaining and strengthening a stable supply system	Stable payout On top of stable dividend payouts, the Company will seek to return profits to shareholders through share repurchases, etc., depending on the circumstances
	•	•	•	•	•	•
	Achieved	Achieved	Not achieved	Achieved	Achieved	Achieved
Achievements	JPY 154.9 billion Net sales (consolidated) (fiscal year) JPY 105.1 billion (2018) JPY 110.4 billion (2019) JPY 154.9 billion (2020) ¹⁾	JPY 52.0 billion (accumulative) Operating income (consolidated) (fiscal year) JPY 16.0 billion (2018) JPY 16.1 billion (2019) JPY 19.9 billion (2020) "	47.5% Capital-to-asset ratio (fiscal year) 48.6% (2018) 45.5% (2019) 47.5% (2020)	JPY 27.1 billion (accumulative) R&D expenditure (consolidated) (fiscal year) JPY 7.9 billion (2018) JPY 8.6 billion (2019) JPY 10.6 billion (2020) "	JPY 22.6 billion (accumulative) Capital investment (consolidated) (fiscal year) JPY 6.0 billion (2018) JPY 6.2 billion (2019) JPY 10.4 billion (2020) "	Stable dividend Dividend per share (fiscal year) JPY 35.8 yen (2018) JPY 44.0 yen (2019) ²⁰ JPY 44.0 yen (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

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



PROACTIVE II

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.

stering talented human resourc



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

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

Broad Product Lineup

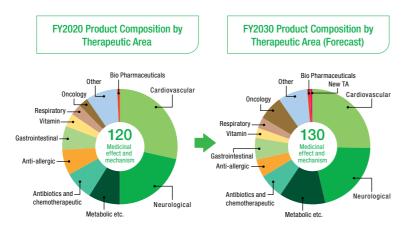
We will put together a generic-drug product lineup with a focus on medicines deemed necessary for future medicinal treatment. We established lineups of products in a broader range of therapeutic areas, and conducted joint sales of Infliximab BS as a steppingstone of entry into the biosimilar market.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

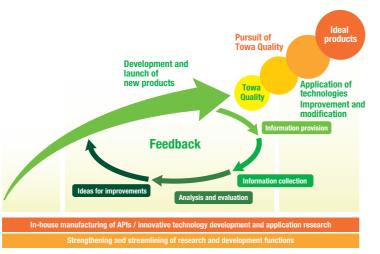
Manufacturing sophisticated products with No. 1 total product performance

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 guality 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.

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.

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 guality and safety.

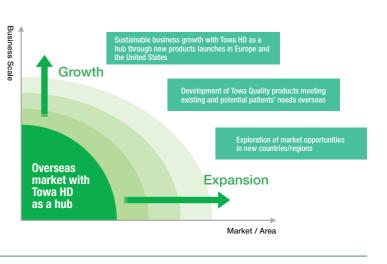




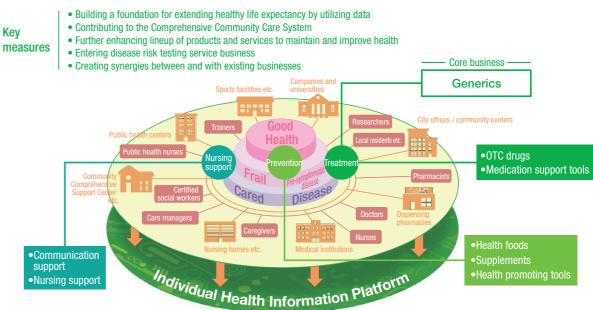
Policy

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.



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,



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

Entering new health-related business

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.

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

API Technology

- 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 Technolog

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

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.

- Pursuing OD tablets that are easy to take
- Further improvement of BACTAB ➡ 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

Creation of New Product Value

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 arowth

Major Objectives

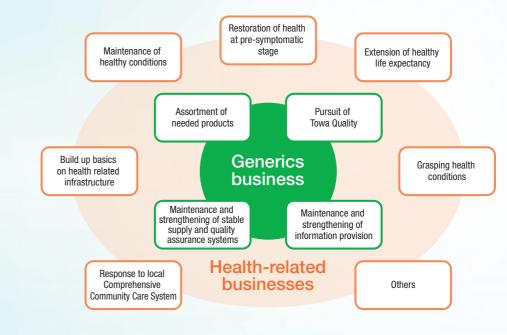
Net sales		Operating income (accumulative)		
JPY 200.0 billion (consoli JPY 150.0 billion (non-cons Achievement of single-year sales	solidated)	JPY 57.0 billion or more Achieving cumulative operating income for the period to invest in sustainable growth and return profits to shareholders		
R&D expenditure (accumulative)	Capital investr	nent (accumulative)	Dividend policy	
JPY 35.0 billion or more Lineup of needed products and improvement of products based on the requests from medical institutions and patients	Investment in strengtl our production facilitie maintain and stre	Ilion or more hening and streamlining es and R&D functions to engthen our quality able supply systems	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



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

SUSTAINABLE G AL



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 healthrelated 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.

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