

## Message from the President

**Nippon Shinyaku provides high-quality, unique products through its Pharmaceuticals business and Functional Food business. In the Pharmaceuticals business, we will create innovative new drugs for patients suffering from illnesses, focusing mainly on disease areas with unmet treatment needs, and ensure that these drugs are delivered to patients. In the Functional Food business, we will provide new value that will be recognized by society through high value-added products that meet market needs. To this end, we will promote global expansion while pursuing even more originality, with the aim of becoming a company with a meaningful existence in the global healthcare field.**

### FY2022 review

While various restrictions on activity due to the COVID-19 pandemic have eased and socioeconomic activities are showing signs returning to normal, the economic outlook remains uncertain due to soaring prices of energy resources and raw materials. Under these circumstances, consolidated revenue for FY2022 totaled ¥144.1 billion, a record high for the 13th consecutive year. On the other hand, both operating profit and profit attributable to owners of parent declined; however, this was due to a one-time factor, namely, loss of one-time revenue from the sale of the priority review voucher in the previous fiscal year, and we believe that we are essentially maintaining our growth trajectory. Total equity as of the end of FY2022 was ¥195.9 billion, and the ratio of equity attributable to owners of parent to total assets was 82.4%, maintaining a high degree of financial soundness.

In the Pharmaceuticals business, in Japan we launched Fintepla for the treatment of epileptic seizures in patients with Dravet syndrome in November 2022, and MonoVer for the treatment of iron deficiency anemia in March 2023; and obtained regulatory approval for a humanized anti-CD20 monoclonal antibody Gazyva for an additional indication of chronic lymphocytic leukemia in December 2022. As for Viltepsa, a treatment for Duchenne muscular dystrophy (DMD) already marketed in Japan and the U.S., we presented long-term data (four years from the beginning of treatment) from a clinical trial conducted in North America at the World Muscle Society in October 2022, thus providing new information to medical professionals.

In the Functional Food business, we launched a new product in our WINZONE series of sports supplements, as well as the anti-aging care supplement Kiwami Select Collagen, which was designed to meet the diverse needs of customers in terms of flavor, quality, and functionality.

### Where and how to develop business in order to fulfill our business philosophy

In fulfilling Nippon Shinyaku's business philosophy of Helping People Lead Healthier, Happier Lives, I focus on the "where" and "how" of our future business development and resolution of social issues.

In the Pharmaceuticals business, "where" refers to disease areas where other companies are not focusing their efforts and where treatment needs have not yet been fully met. "How" refers to the provision of new drugs and value by leveraging new modalities such as gene therapy in addition to our unique fundamental technologies for drug discovery related to small molecule compounds and nucleic acid drugs.

As a manufacturer of new drugs, one of our challenges is to obtain returns on major investments that are essential in promoting our business activities, such as R&D expenses. We believe that we can solve this problem by expanding our business globally in order to deliver needed drugs to patients around the world who are suffering from diseases.

In the Functional Food business, we leverage our advanced technical expertise as a pharmaceutical company to supply highly original products in the bulk materials business for health food ingredients, preservatives, and protein preparations, as well as in the supplements business. Going forward, we will promote global expansion, with a focus on East Asia and Southeast Asia, where economic growth is remarkable.

➔ P. 22 Value Creation Process



**We will continue to promote global expansion to deliver satisfaction to patients around the world and all those who support them.**

**Toru Nakai**  
Representative Director, President

## Message from the President

### Revision of issues of materiality

In 2021, Nippon Shinyaku identified its issues of materiality as matters deemed important for solving social issues and creating value. In recent years, as social conditions and the environment surrounding our Company have changed significantly and sustainability has become even more important, we revised the issues of materiality in March 2023. In proceeding with the revision, we considered the future of Nippon Shinyaku and thoroughly discussed what the issues are, what needs to be addressed, and what we should do to solve these issues. Going forward, we will continue to revise our issues of materiality on an ongoing basis in order to respond flexibly to changes in the social environment and to create sustainable value.

➔ P. 20 Materiality

### Human resources to support sustainable growth

Employees are a company's most important asset. As a manufacturer of new drugs, we believe that developing diverse human resources and realizing employee well-being is essential for creating innovation and realizing sustainable growth, which was established in the revision of issues of materiality.

To cite an example of human resource development, we have launched the NS Academy, a new human resource development program that values self-directed learning, in order to provide an environment in which each individual can learn autonomously with their own future in mind, as opposed to the conventional method of putting all employees through the same training program. In addition, we are also recruiting highly specialized mid-career hires, with a particular focus on those who will promote global expansion.

Nippon Shinyaku also puts effort into promoting health and ensuring safety in the workplace so that our employees can lead happier and better lives, and in FY2022, we established the Well-being Promotion Section. The Well-Being Promotion Section is based on the three axes of "knowing your own well-being," "knowing the well-being of those around you," and



"deepening your understanding of well-being," and is working to promote well-being internally through messages from the president and various events such as online courses. In addition, we will continue to discuss with outside advisors about how we should promote well-being at Nippon Shinyaku.

➔ P. 52 Human Resources Development

### Promoting patient-centered business activities

In order to share our mission and values throughout the organization, I make a point to use the term "patient centricity" in the hopes of promoting patient-centered activities. Therefore, when we revised our issues of materiality, we explicitly described the concept of patient centricity and the activities that lead to it.

Due to the highly specialized nature of the healthcare field, there are very large disparities in the amount of information and knowledge between patients and medical professionals, such as doctors. In the U.S., pharmaceutical companies can advertise prescription medicines to patients, and NS Pharma, our Group company in the U.S., provides information to patients through events organized by patient organizations. In Japan, pharmaceutical companies are currently restricted from providing information on prescription medicines directly to patients, but the industry as a whole is beginning to consider business activities that incorporate patients' perspectives. At Nippon Shinyaku, we have launched a

cross-divisional project to examine which specific activities promote patient centricity. In addition, we are fostering the awareness of each and every employee to incorporate patient feedback into our corporate activities. For example, the industry is considering initiatives such as conducting clinical trials without the use of placebos, especially in Phase III trials, for patients with serious diseases. Through communication with patients, their families, and patient organizations, we are also considering clinical trial protocols that take the patient's perspective into account.

Currently, DMD patients in countries and regions other than Japan and the U.S. who wish to receive Vilepso must participate in clinical trials, but their participation may be restricted due to age and other requirements. In 2021, in order to provide the drug continuously to patients who are unable to participate in clinical trials or who have completed clinical trials, we implemented the Vilepso Managed Access Program. In addition to aiming for early approval in countries and regions outside of Japan and the United States, we will make Vilepso available to as many patients as possible around the world as soon as possible through this managed access program.

### Three commitments to achieve medium- and long-term growth

In order to keep pace with the diversification of drug discovery modalities, the globalization of the market, and the diversification of individual work styles and values, I set out our three commitments when I became president in 2021: Continue to launch at least one unique product each year; generate at least 50% of consolidated sales from overseas; and, target at least 100% gains in sales and operating profit.

#### Continuously launch new products to increase corporate value

For R&D-led new drug manufacturers, corporate value is largely determined by the development pipeline, which is the driver for future growth. In a few years, the patent for Upravi, which has been driving Nippon Shinyaku's growth, will expire. Since it

is necessary to continuously launch new products to overcome this patent cliff, we are expanding our development pipeline through three R&D approaches: in-house drug discovery, in-licensing, and product life-cycle management (PLCM).

As for drugs discovered in-house, our new nucleic acid drugs for DMD following Vilepso, NS-089/NCNP-02 and NS-050/NCNP-03, have advanced to the clinical trial stage. In the area of small molecule compounds, NS-018 for myelofibrosis, NS-580 for endometriosis and chronic prostatitis/chronic pelvic pain syndrome are in Phase II trials; NS-229 for eosinophilic granulomatosis with polyangiitis is in preparation for Phase II trials; and NS-161 for inflammatory diseases and NS-025 for urological diseases are in Phase I trials. In addition, we have established a new overseas R&D center, Innovation Research Partnering (IRP), in Cambridge, Massachusetts. By increasing our access to the world's most advanced drug discovery and other technologies, we expect to accelerate our in-house drug discovery research and build a more diverse R&D portfolio.

We are also actively investing in licensing activities, including in-licensing and alliances for products on the market and drug candidates still under development. For the cell therapy CAP-1002, for which Capricor Therapeutics, Inc. is currently conducting Phase III trials in the U.S. for DMD, we entered into an exclusive partnership for distribution in the U.S. in January 2022, and for distribution in Japan in February 2023. As for progress in Japan, in June 2023, we filed an application for the approval of NS-87 for the expected indication of high-risk acute myeloid leukemia. In the same month, our partner company UCB S.A. filed an application for an additional indication of Fintepla for Lennox-Gastaut syndrome.

In the area of PLCM, we are expanding the indications of Upravi (NS-304) for pediatric pulmonary arterial hypertension



Building where IRP office is located

## Message from the President

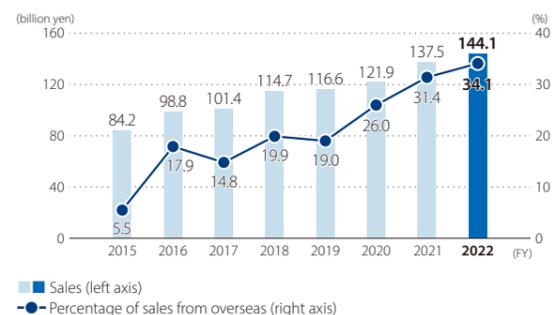
and arteriosclerosis obliterans, and Gazyva (GA101) for lupus nephritis and pediatric nephrotic syndrome. We will continue to actively develop additional indications and new dosage forms to meet the needs of patients and the medical practice field, and try to maximize the value of our products.

➔ P. 34 Pharmaceuticals Business

### Promote global expansion through our own marketing and collaboration with partner companies

In Japan, the pharmaceutical market is experiencing sluggish growth due to a declining population and policies to curb medical expenses, such as the annual price revision by MHLW. However, Nippon Shinyaku aims to achieve sustainable growth by promoting global expansion and increasing the ratio of overseas sales. In overseas markets, for disease areas where the estimated number of patients is above a certain level, we will prioritize collaboration with partner companies that have a broad sales network. On the other hand, for disease areas where the number of patients is very small and the number of medical facilities to which we provide information is relatively limited, we are considering strategies that could include our own marketing. To give a specific example, Upravi is currently sold in more than 70 countries overseas by our partner company to which it is out-licensed. As for Viltepso, I myself was stationed in the U.S. and spent about two and a half years establishing our own marketing system for the product. Although the launch of Viltepso in the U.S. market was slightly delayed due to the impact of the COVID-19 pandemic, our overseas sales ratio in FY2022 reached approximately 34%. We will strive to achieve our overseas sales ratio target of 50% as soon as possible by carefully analyzing regulatory approval

### Sales and percentage of sales from overseas



systems and drug pricing systems and aggressively developing products in other countries and regions, including Europe and China.

➔ P. 12 Global Expansion

### Toward strengthening our foundation for medium- to long-term growth

FY2023 is the final year of the 6th Medium-term Management Plan and also the formulation year of the 7th Medium-term Management Plan. During the 6th Medium-term Management Plan period, revenue was affected by the COVID-19 pandemic, but we made the decision to invest for future growth without reducing R&D expenditures in order to promote global development of nucleic acid drugs and other products. We believe that the increase in the percentage of in-house developed products in our development pipeline is the result of our aggressive R&D efforts. In addition, we were able to build a foundation for global expansion by establishing our own marketing system for Viltepso in the U.S. and establishing Group companies in China for the purpose of building our own marketing system there. We believe that we have been able to firmly address what needed to be addressed, and that we have been able to build a management foundation and identify issues for the next medium-term management plan.

Strengthening the foundation for making profits not only in the Japanese market but also in the global market will continue to be a major theme for us. We hope to clearly draw up in our 7th Medium-term Management Plan the roadmap that will serve as the foundation for becoming a company with sales of ¥300 billion and, in the future, a company with sales of ¥500 billion.

➔ P. 24 Medium-term Management Plan

### Aiming to solve management issues by further promoting DX

Nippon Shinyaku obtained the DX certification from the Ministry of Economy, Trade and Industry of Japan in March 2022 and established the DX Division in the following April to



promote company-wide digital transformation (DX). The Digital Transformation Promotion Committee, which I chair, was established to visualize management and operational issues and solve them through the use of digital technology and data. The committee is working on a top-down basis to determine important DX themes that will serve management and to achieve them. Currently, there are 16 DX themes related to R&D, sales activities, production activities, etc. in progress. In the area of R&D, we are considering initiatives such as actively using AI to search for new compounds and using wearable devices to confirm drug efficacy. For production, we have begun using AI in demand forecasting and are also moving forward with a connected factory design that utilizes AI and IoT. These efforts have only just begun, but we intend to accelerate the transformation by focusing on training data scientists and other human resources who will be responsible for promoting DX.

In addition, we have formed a DX Team consisting of members with high IT literacy, aiming to visualize and solve business issues on-site in each department as a bottom-up activity. In FY2022, we planned the DIS\* Challenge 2022 to foster a company-wide culture of taking on challenges. The ideas proposed in this project are reviewed by outside experts

and the DX Division, and those ideas that receive high evaluations are being implemented in our operations.

\* DIS: Abbreviation for "digital ideas for smiles," a project to come up with DX ideas to bring smiles to people.

## Message to stakeholders

I encourage all employees to step out of their comfort zone and into their learning zone, to keep challenging themselves to grow for the sake of bringing smiles to patients. In a rapidly changing society, we must envision what lies ahead, create new challenges, and move forward along the path less traveled. People grow by stepping out of their current comfort zone and placing themselves in a learning zone. We will build an organization that encourages taking on challenges more than ever before, including new personnel system reforms.

We will work to meet stakeholder expectations by engaging in active communication and dialogue about our efforts. I ask all stakeholders for their continued understanding and support for Nippon Shinyaku.