

Message from the President



Toru Nakai
Representative Director, President

Creating various types of new “ways of life” for each person around the world

Nippon Shinyaku aims to contribute to creating healthy and fulfilling lives through two businesses: Pharmaceuticals and Functional Food. To realize our “Vision for 2035,” we will use the 7th Five-Year Medium-Term Management Plan formulated in April 2024 as a new starting point, aiming to increase sustainable corporate value by providing high-quality and distinctive products and services.

Our long-term “Vision for 2035” that responds to diversifying “ways of life” needs

We anticipate that our business environment will continue to change dramatically due to advancement in research and development, progress in AI and digital technologies, diversification of values, as well as declining birthrate, aging population, and population decrease in Japan, and strengthening of medical cost containment measures. Under these circumstances, we believe it is important to view the world as a growth market, to respond quickly to advancing technologies with the progressive spirit of a Kyoto company, and to seriously address the diversifying needs of “way of life” by providing distinctive products and services. Based on the business environment and our Business Philosophy, we have set our “Vision for 2035” as “a global healthcare company from Kyoto creating various types of new ways of life for each person around the world.” Amidst diversifying ways of thinking and living, we aim to contribute to society based on our Business Philosophy of “Helping People Lead Healthier, Happier Lives.” Through our Pharmaceuticals and Functional Food Businesses that contribute to “ways of life,” we will provide differentiated products and services and create the joy of living and new “ways of life” to patients and their families worldwide.

Review of FY2023 and the 6th Five-Year Medium-Term Management Plan

In the Pharmaceuticals Business, royalty income from overseas sales of Upravi, a treatment for pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension, and Viltepso, a treatment for Duchenne muscular dystrophy (DMD), grew, and in the Functional Food Business, sales of supplements and protein formulations increased. As a result, the Group's revenue for FY2023 increased by 2.8% year-on-year to 148,255 million yen. In terms of profit, operating profit increased by 10.8% year-on-year to 33,295 million yen due to increased revenue and lower cost of sales ratio resulting from sales composition, achieving record highs in both sales and profit.

Regarding the launch of new products, we obtained approval for Vyxeos, a treatment for high-risk acute myeloid leukemia, in March 2024 and began domestic sales in May. For Fintepla, a treatment for epileptic seizures associated with Dravet syndrome, our partner UCB obtained additional approval for Lennox-Gastaut syndrome, and we are responsible for providing information in Japan.

The overseas sales ratio for FY2023 was 42.6%, up from 34.1% in FY2022. The pillars of overseas sales are our own sales of Viltepso in the U.S. and royalty income from overseas sales of Upravi by our licensee, which we expect to grow further until the patent expiration of Upravi.

In the 6th Five-Year Medium-Term Management Plan, we aimed to increase our social significance by becoming a

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“company with a meaningful existence in healthcare field” and took on six initiatives. As a result, we achieved outcomes such as launching more than one new product per year on average, starting our own sales of Vilepso in the U.S., obtaining SBTi approval, continuous certification as a “Health & Productivity Management Outstanding Organization (White 500),” and obtaining DX certification, making it a five-year period of significant growth. On the other hand, issues such as the speed and success rate of clinical development, room for improvement in sales capability overseas, and insufficient speed in research and development of new modalities have become apparent. In the “7th Five-Year Medium-Term Management Plan,” we will work to resolve these identified management issues.

Aims of the 7th Five-Year Medium-Term Management Plan

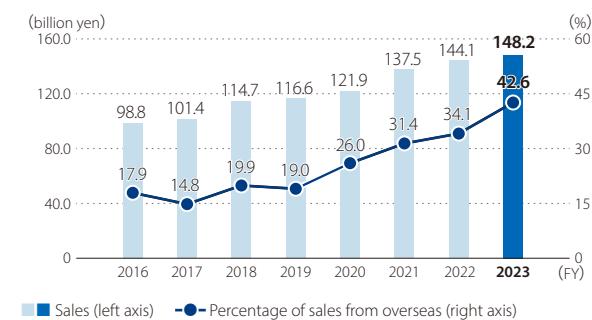
In April 2024, we launched the “7th Five-Year Medium-Term Management Plan ~For Global Growth Beyond the Cliff~.” The 7th Medium-Term Management Plan is a guideline for future growth beyond the patent cliff of Upravi, which has driven our growth, and is formulated as a scenario to further strengthen the foundation for providing Nippon Shinyaku's unique products and services to the world. We also believe it will lead

to resolving the material issues revised in 2023 and serve as immediate efforts to realize our “Vision for 2035.”

Our Company achieved significant growth with our in-house developed product Upravi, but we expect a significant decrease in royalty income due to patent expiration in FY2028. During the 7th Medium-Term Management Plan period (FY2024-2028), although we anticipate a temporary decrease in profit due to prioritizing investments for future growth, we will focus on establishing a revenue base that does not depend on royalty income, overcoming the patent cliff. We expect to launch products that will become global growth drivers in the latter half of the 7th Medium-Term Management Plan period, aiming for revenue of 230 billion yen, operating profit of 30 billion yen, and ROIC of 9% or higher in FY2028. After 2028, by growing overseas sales more than domestic sales, we aim to become a company with revenue of around 300 billion yen, operating profit of around 50 billion yen, and an overseas sales ratio of 50% or higher in FY2030. This is a scenario to achieve two of the three commitments I made when I became president: “overseas sales ratio of 50% or higher” and “doubling both sales and operating profit from FY2020 levels.”

In the 7th Medium-Term Management Plan, we will manage both Pharmaceuticals and Functional Food Businesses with ROIC as an indicator, conscious of capital efficiency exceeding the cost of capital, through “Three key themes” and “Strengthening five management foundations.”

Sales and percentage of sales from overseas



Toward expanding global development

To deliver necessary medicines to patients worldwide, we will further promote global expansion by considering means such as in-house sales, alliances, and M&A.

In the U.S., we are currently conducting in-house sales of Vilepso through our Group Company NS Pharma, Inc. (NS Pharma). As we plan to launch multiple DMD treatments including cell therapy in the future, we aim to expand sales by preparing an environment for prompt penetration.

Also, to promote business development in China, we established Beijing Nippon Shinyaku Co., Ltd. and Tianjin Nippon Shinyaku Co., Ltd. in 2021. Currently, we are conducting sales activities mainly with our in-house developed gastric mucosal protective agent as the main product while developing our business structure and accumulating business know-how. We are preparing for the future sales of Vilepso by recruiting necessary talent, carrying out marketing, and preparing patient access including pricing strategies in anticipation of public insurance reimbursement. In Europe, we are considering various options including building our own sales structure or strategic partnerships with partners.

Maximizing individual potential and utilizing digital technology to respond to global expansion

Anticipating an increase in workload due to further promotion of global expansion, we plan to acquire talent capable of global activity and increase locally hired staff at overseas locations. On the other hand, in Japan, we will promote organizational culture reform to maximize individual potential and allow each person's individuality to be expressed.

We will also actively invest in developing digital talent and systems to transform operations and improve productivity through digitalization. At Nippon Shinyaku, we define “transformative talent” as those who can identify issues and create fundamental business reforms or new businesses by utilizing digital technology and business skills. Transformative talent will acquire skills to respond to issues arising in daily

operations such as research and development and promotional activities based on data, realizing efficiency. Furthermore, the management has defined 18 priority “DX (Digital Transformation) themes,” with inside directors serving as project owners to promote them and drive Company-wide transformation. The activities and progress of the “DX themes” are regularly confirmed in the “Digital Transformation Promotion Committee,” where all internal directors serve as members and I serve as the chairman. During the internal digital month in October 2023, project leaders of each theme reported progress to all employees to enhance understanding of DX initiatives across the Company.

Nippon Shinyaku's values: Patient centricity

To promote patient-centric business activities, Nippon Shinyaku emphasizes thoughts and activities based on patient centricity. Patient centricity means always placing patients at the center of healthcare, focusing on patient-centric responses, and ultimately respecting patients' decisions to the maximum extent.

Nippon Shinyaku is advancing research and development through three approaches: in-house drug discovery, in-licensing, and Product Life Cycle Management (PLCM), based on fundamental technologies such as nucleic acid drugs and small molecule drugs. At the center of this is the patient-centric perspective of what we can do for patients and what patients want us to resolve. In my daily management, I use “Will it benefit patients and their families?” as one of my decision-making criteria. I value this perspective not only in research and development, supply chain, and sales departments but also in administrative departments, aiming to realize a healthy future for patients and those who support them.

From FY2023, we launched a Patient Centricity Project consisting of members from various departments, conducting activities including internal awareness-raising. We will continue to listen to patients' voices through events such as e-sports tournaments for children with disabilities, in-house lectures by patients' families, and public seminars, striving to engage in activities that are as close to patients as possible.

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eSports tournament in action

The desires to give one's all of each individual are the source of innovation

Our Company respects diversity and provides opportunities for each individual to take on challenges positively and grow. We believe that by fostering an organizational culture where employees with diverse values can work vibrantly and realizing well-being, we can generate innovation and achieve sustainable growth.

Employees' desires to give one's all are the most powerful management resource. Based on these desires, it is necessary for each employee to utilize their individuality and strengths, work together, and for the entire Company to become one team to maximize performance. "NS Mind" specifically expresses this idea, showing the attitudes and awareness that all employees should aim for, targeting "self," "others," and "society." Under "NS Mind," we aim for the further growth of Nippon Shinyaku by having all employees grow more than ever before.

Dear Stakeholders

To gain further trust from stakeholders and society and lead to increased corporate value, we will work on strengthening information disclosure. From April 2024, we established an IR Promotion Section in the Corporate Planning Department to conduct IR activities exclusively, aiming for more proactive information disclosure than ever before. Also, in June, we introduced a restricted stock compensation system that allocates our common shares according to performance, to provide incentives for directors to sustainably increase corporate value and to further promote value sharing with shareholders.

Nippon Shinyaku aims to realize a society where patients and their families worldwide can spend time with smiles by developing and delivering treatments for areas and fields with unmet treatment needs. Upravi, which we started selling in the U.S. in 2016, is currently sold in more than 70 countries through partner companies and has become a blockbuster drug with annual sales exceeding \$1 billion. For Viltepso, which we started selling in the U.S. in 2020, we built our own sales structure centered on NS Pharma. In this way, we consider partnerships with partner companies or in-house sales for each product and country we expand into, aiming to deliver necessary medicines to patients worldwide in the most optimal way.

While there are many global companies in Kyoto, we aim to join their ranks and be recognized worldwide by 2035. To this end, we will work at full speed toward developing unique products that only Nippon Shinyaku can create and a future that Nippon Shinyaku can create because of who we are. I ask all stakeholders for their continued understanding and support for Nippon Shinyaku.

Promotion of Global Business

Activities in the United States

The Duchenne muscular dystrophy treatment Viltepso is the first product that Nippon Shinyaku has sold in-house in the U.S. To promote our global business, we are strengthening our organizational structure in research and development, supply chain, medical, and sales in cooperation with our Group Company NS Pharma in New Jersey, U.S.

R&D and business development activities

We are developing multiple products globally, including Viltepso and subsequent exon-skipping drugs, and NS Pharma plays the role of a global base for clinical development and business development activities. In building our research and development structure, we are actively recruiting talent with experience in rare disease development and FDA regulatory affairs.

We also opened "Innovation Research Partnering (IRP)" in Cambridge, U.S., one of the world's largest innovation hubs, in 2023. By placing a base for exploring drug discovery seeds and technologies here, we aim to increase access to the world's most advanced drug discovery technologies and seeds, accelerate our in-house drug discovery research, and build a diverse research and development portfolio.

Drug cost reimbursement

In the U.S., each patient is enrolled in private or public insurance, with different out-of-pocket expenses. There is also a certain number of uninsured patients. Given this background, if insurance organizations do not approve reimbursement for medications in the U.S., patients would have to bear the full cost of the drug, making it difficult to reach actual prescription. Therefore, pharmaceutical companies negotiate drug reimbursement with individual insurance organizations, and NS Pharma's Market Access Department is responsible for this role. By negotiating primarily with major private insurance companies and public insurance organizations, we are working to establish favorable reimbursement policies (criteria for recognizing insurance reimbursement) for Viltepso drug cost reimbursement.

Comprehensive patient support service "NS Support"

In order to receive insurance reimbursement for Viltepso, patients must attend a specialized medical institution for genetic testing and motor function evaluations. Due to the vast size of the U.S., many patients who find it difficult to attend

such medical institutions receive in-home administration of Viltepso. In these cases, making practical arrangements for drugs and coordination with hospitals is essential, but maintaining these arrangements is a major burden for patients. NS Pharma provides a comprehensive patient support service called "NS Support," led by the Patient Support Department, to reduce the burden on healthcare professionals, patients, and their families. This service supports insurance reimbursement procedure guidance and assistance, and arrangements for medication and nurses for home injection treatment.

Provision program in unapproved countries

Currently, Viltepso is marketed in Japan and the U.S. only. When patients in other countries and regions wish to receive Viltepso, one way to do so is by participating in clinical trials. However, the number of patients who can participate in clinical trials is limited, and there was concern that after the trial ends, there would be no opportunity for administration until Viltepso is approved in that country. Therefore, we launched the "Viltepso Managed Access Program" in 2021 in order to provide the drug on an ongoing basis for patients who have participated in and completed clinical trials, as well as to those who are unable to participate.



NS Pharma