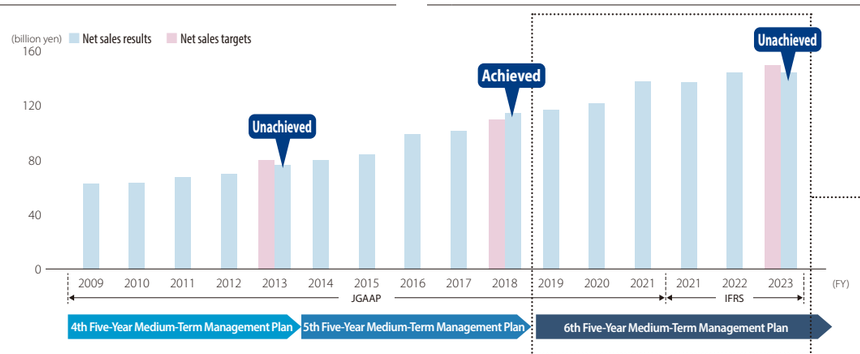
Review of Medium-Term Management Plans (4th–6th)

In the 6th Five-Year Medium-Term Management Plan "Aiming for Sustainable Growth—Pursuit of Further Originality—," which started in FY2019, we took on the challenge of "six actions" to become a company with a meaningful existence in the healthcare field. As a result, we were unable to achieve management targets in the 6th Five-Year Medium-Term Management Plan.

However, we established a foundation for global expansion through working on our own marketing in the U.S. and China, and achieved sustainable growth with record high revenue and respective profits in FY2023.

Nippon Shinyaku's Vision

A company with a meaningful existence in the healthcare field

	4th Five-Year Medium-Term Management Plan FY2009–2013	5th Five-Year Medium-Term Management Plan FY2014–2018
Scenario	"Innovation and Growth"	"Aiming for New Growth –Pursuit of Originality–"
Business metrics	**FY2013 results** Net sales ¥76.5 billion Operating income ¥8.0 billion Net income attributable to owners of the parent ¥5.7 billion	**FY2018 results** Net sales ¥114.7 billion Operating income ¥20.6 billion Net income attributable to owners of the parent ¥16.3 billion EPS ¥242 ROE 12.5%
Main results	• Expansion of pipelines for in-house drugs • Investment in detailing based on clear allocation of resources in response to promotion of generics; steady progress with new products • Expansion of Functional Food Business • Cumulative cost-reduction target of about ¥2.0 billion achieved for 5 years • Creation of CASA (CAreer Support Academy) for development support and training • Social contribution initiatives	• Launch of seven products, including Uptravi for pulmonary arterial hypertension (PAH) • Pipeline enhancement through conclusion of in-licensing agreements for six products • Greater awareness of Nippon Shinyaku in PAH field • Major contribution to growth from the launch of Uptravi in multiple overseas markets • Significantly increased sales and higher operating margin achieved in Functional Food Business • Flextime system introduced for MRs (industry first in Japan) • Outside specialist personnel recruited
Tasks for the next MTMP	• Establish clear differentiation with rivals by building base of innovation to achieve sustained growth amid shifts in external conditions such as healthcare spending restrictions and falling birth rates • Achieve targets through launches of new products and profitability improvements; link qualitative and financial targets	• Pursue technological innovation to create new value by supplementing the existing drug discovery base for targeting small molecules and nucleic acid drugs with new modalities and technologies • Re-invest profits generated by Uptravi in NS-065/NCNP-01 and successor nucleic acid drugs, NS-018, and other drugs, to support accelerated global development
Net sales trend		

6th Five-Year Medium-Term Management Plan FY2019–2023

"Aiming for Sustainable Growth –Pursuit of Further Originality–"

	FY2023 Targets	FY2023 Results
Revenue	¥150.0 billion	¥148.2 billion
Pharmaceuticals	¥133.0 billion	¥125.1 billion
Functional Food	¥17.0 billion	¥23.1 billion
Operating income	¥40.0 billion	¥33.2 billion
Net income attributable to owners of the parent	¥30.0 billion	¥25.8 billion
EPS	¥445	¥383
ROE	10% or more	12.4%

Results and issues for six actions

1	Creation of new value through R&D	Results	• Launch of Defitelio for sinusoidal obstruction syndrome, Viltepso for Duchenne muscular dystrophy, Fintepla for seizures associated with Dravet syndrome and Lennox-Gastaut syndrome, and MonoVer for iron deficiency anemia • Gained regulatory approval for the additional indications of acute myeloid leukemia for Vidaza and chronic thromboembolic pulmonary hypertension (CTEPH) for Uptravi
		Issues	• Speed and probability of success rate in clinical development • Research on new modalities
2	Development of global business	Results	• Launch of our products (Viltepso (U.S.) and Gaslon N (China)) through overseas subsidiaries • Established Innovation Research Partnering (IRP), a drug discovery center in the U.S.
		Issues	• Marketing capabilities for Viltepso in the U.S. • Capture U.S. market share for Viltepso
3	Increase in corporate value by strengthening ESG management	Results	• Declared support for the TCFD recommendations and started disclosing information based on those • Selected as constituent stock in FTSE Blossom Japan Sector Relative Index • Acquired SBTi approval for greenhouse gas emission reduction targets
4	Creation of organizational climate in which every employee can flourish	Results	• Introduced flextime throughout the Company and continued to make use of telework • Introduced a second job system to encourage the acquisition of diverse knowledge and skills by employees and career autonomy and independence • Acquired "White 500" Health & Productivity Management Outstanding Organization
5	Active use of AI and adoption of IT	Results	• Acquired Digital Transformation Certification from the Ministry of Economy, Trade and Industry • Created environment for data-driven drug discovery through promotion of IT and introduction of AI in the Research Department
6	Further strengthening of management base	Results	• Adopted International Financial Reporting Standards (IFRS) to increase international comparability of financial information

7th Five-Year Medium-Term Management Plan

The 7th Five-Year Medium-Term Management Plan was formulated based on a scenario of generating growth by overcoming the loss of the Uptravi patent, which expires in FY2028, and further strengthening our foundation for providing products and services globally with thinking about the life of each patient and customer as we strive to realize our "Vision for 2035." After resolving the issues that came to light in the 6th Five-Year Medium-Term Management Plan, we will unite to boldly take on the challenge of tackling "Three key themes" and "Strengthening five management foundations." In FY2028, the final year of the 7th Medium-Term Management Plan, we will achieve our "Vision for 2035," having completed all the preparations to become a company with revenue of ¥300.0 billion and operating income of ¥50.0 billion in FY2030.

The 7th Five-Year Medium-Term Management Plan
FY2024 - FY2028

Targets in FY2028	Revenue 230.0 billion yen		Operating profit 30.0 billion yen	
	EPS 341 yen		ROE 8% or more	ROIC 9% or more
Three Key Themes	I Fostering growth drivers to replace Uptravi		II Expanding global development	III Continuous pipeline expansion
Strengthening Five Management Foundations	(1) Promoting sustainability management for realizing sustainable society	(2) Speeding up R&D	(3) Promoting human capital management that allows each employee to grow and diverse human resources to play an active role	(4) Business process reengineering and productivity improvement by promoting digitalization / (5) Financial strategy for sustainable growth

Business Strategy

Pharmaceutical Segment

Launching an average of two or more new products per year through the three pillars of in-house drug discovery, in-licensing, and PLCM, prioritizing response to the patent cliff.

In-house Drug Discovery, PLCM
Focus on nucleic acid and small molecule drug discovery, concentrate management resources on diseases and areas where we can aim for global expansion

In particular, nucleic acids will be focused on DMD and non-DMD diseases, with the aim of bringing products for non-DMD diseases to market by 2035

In-licensing
Give priority to items that can be sold globally and capture at least one in-licensed product each year

Sales
Based on global marketing, consider and promote the best way to proceed with out-licensing, self-sales, etc., in each country to quickly launch products and increase market share in each region

Pharmaceutical Business Segment Targets

FY2028

Revenue	¥203.0 billion
Operating profit	¥28.2 billion
ROIC	≧9%

Functional Food Segment

Transition to a stable, highly profitable structure by providing high quality, unique materials and final products that offer high value added.

B to B Business
Focus on preservatives, for which demand is expected to increase as reducing food loss draws greater attention from a sustainability perspective

B to C Business
Further accelerate growth of sports supplement WINZONE Whey Protein and enhance lineup of anti-aging care supplements by developing new products

Overseas Expansion
Establish systems for business development in Asian countries and other overseas markets

Functional Food Business Segment Targets

FY2028

Revenue	¥27.0 billion
Operating profit	¥1.8 billion
ROIC	≧9%

Three Key Themes and Strengthening Five Management Foundations

To overcome Uptravi's patent cliff and achieve sustainable growth, we will engage in "Three key themes" and in "Strengthening five management foundations" supporting them through the promotion of the Pharmaceuticals Business and the Functional Food Business.

Three Key Themes

I. Fostering growth drivers to replace Uptravi
We will launch on average two or more items annually as growth drivers during the 7th Medium-Term Management Plan and achieve early market penetration. These items include ones from the DMD products globally (CAP-1002, NS-089/NCNP-02, NS-050/NCNP-03, and NS-051/NCNP-04), new hematologic cancer products in Japan (Vyxeos, Jaypirca, and NS-401), and product life cycle management (PLCM) products (Gazyva for renal disease, Fintepla, and Uptravi for pediatric and high-dose formulations). We also aim to introduce on average two or more new products from the group of products that have already started clinical trials, in-licensed products, and PLCM. Furthermore, we will expand the number of items on the market even more by focusing on acquiring new in-licensed products.

As for our domestic sales strategy, we aim for quick market penetration of products by adding forms and indications and introducing new products with a focus on the priority areas of hematology, pulmonary hypertension, and pediatric neurology. At a time of changes in the work styles of physicians, we will deliver products to even more patients by promoting omni-channel activities that leverage the MR channel and digital channel.

We aim to generate global revenue of ¥130.0 billion or more in the above mentioned three priority areas in FY2028 by undertaking both sales promotion activities in Japan and global marketing of nucleic acid drugs following CAP-1002 and Viltepso.

II. Expanding global development
In addition to the already-launched Viltepso, the U.S. subsidiary NS Pharma plans to launch several DMD treatments, including the cell-therapy CAP-1002. With an eye toward quickly launching these products, the Company is focusing on expanding effective, efficient marketing and services that support patients.

In addition to preparing to launch Viltepso through the two Chinese subsidiaries Beijing Nippon Shinyaku Co., Ltd., and Tianjin Nippon Shinyaku Co., Ltd., we are moving forward with building a functional food marketing system.

In order to provide patients around the world, not only the U.S. and China, with our products, we are accelerating our global expansion by examining various methods, including

New product launch targets

	FY2024	FY2025	FY2026	FY2027	FY2028
Japan	NS-87 (Vyxeos): high-risk AML		NS-401: BPDCN	NS-089/NCNP-02: DMD	NS-050/NCNP-03: DMD
	LY3527727 (Jaypirca): MCL		ZX008 (Fintepla): CDKL5 gene deficiency	GA101 (Gazyva): SLE without nephropathy	NS-051/NCNP-04: DMD
	NS-304 (Uptravi): pediatric PAH		GA101 (Gazyva): lupus nephritis		
			GA101 (Gazyva): pediatric nephrosis		
Overseas			CAP-1002 (U.S.): DMD	NS-089/NCNP-02 (U.S.): DMD	NS-050/NCNP-03 (U.S.): DMD
					NS-051/NCNP-04 (U.S.):DMD
					NS-065/NCNP-01 (EU, CN): DMD

AML: acute myeloid leukemia; MCL: mantle cell lymphoma; PAH: pulmonary arterial hypertension; BPDCN: blastic plasmacytoid dendritic cell neoplasm; DMD: Duchenne muscular dystrophy; SLE: systemic lupus erythematosus

7th Five-Year Medium-Term Management Plan

in-house sales, alliances, and M&As. When accelerating our global expansion, we promote business that has a global perspective and work to reinforce our global handling of such issues as the reliability assurance system and supply chain. In the U.S. and China, where we are building marketing systems, we promote licensing activities with an eye toward sales of in-licensed products. Through these activities, we will establish a system that makes it possible to provide and sell multiple pharmaceuticals globally.

III. Continuous pipeline expansion

We will continue to expand our pipeline, primarily through in-house drug discovery, in-licensing, and PLCM.

As for in-house drug discovery, we are working to strengthen this by combining our strengths with new and outside technology. Leveraging open innovation and AI drug discovery, we are moving forward with nucleic acid drug discovery (DMD and central nervous system) and small molecule drug discovery (hematology, intractable/rare diseases, urology and gynecology diseases). Although our nucleic acid drug discovery has mainly focused on Duchenne muscular dystrophy, we also undertake drug discovery in the central nervous system area, and aim to enter clinical trials in FY2026. For nucleic acid drug discovery, we believe that the utilization of new drug discovery modalities, especially through open innovation, will become important, and will promote initiatives to broaden the scope of drug discovery, such as joint research with outside entities.

For in-licensing, priority is given to items that will lead to global sales, and our goal is to acquire more than one in-licensed item in post-clinical trial phase every year.

Turning to PLCM, we will begin working on clinical trials for a second indication quicker than previously to maximize the value of the drug.

Strengthening Five Management Foundations

(1) Promoting sustainability management for realizing sustainable society

It will be impossible for us to survive unless we realize a sustainable society. While promoting sustainability management to realize a sustainable society, we actively work to solve five material issues.

In addition, we aim to be trusted by society as a global healthcare company from Kyoto creating various types of new ways of life for each person around the world by actively disclosing our initiatives related to environment and social issues, which is primarily the responsibility of an IR-dedicated department established in April 2024.

(2) Speeding up R&D

In drug discovery research, we aim to shorten the time from the conception of a theme to its entry into clinical trials, and to establish a system that enables us to launch one in-house product each year.

Therefore, we not only prioritize projects, allocate management resources, and review decision-making meetings but also promote the use of AI. By reducing the time it takes researchers to conduct research and prepare inferences using AI, we are trying to speed up the drug discovery research cycle and link that to the early launch of research activities.

As for delays in clinical research, one of the issues that came to light during the 6th Five-Year Medium-Term Management Plan, we are working to speed up the process by strengthening project management, pursuing the possibility of early approval, and improving probability of success.

Environment	• Greenhouse gas emission reduction target (FY2030) Scope 1+2: -42% (compared to FY2020)　Scope 3 Category 1: -25% (compared to FY2020) • Resource management and resource recycling Percentage of recycle waste plastic: 65% or more Continuous reduction of water consumption per ¥100 million in sales
Society	• Reduce human rights risks by implementing human rights due diligence, etc. • Continuous contributions to healthcare through public research grant system
Governance	• Strengthening the global governance system　• Strengthening risk management framework

<Speeding up clinical development>

Strengthen project management	• Strict progress check across management • Improve negotiation skills with overseas authorities by hiring qualified medical doctors • Building a clinical development system that can respond flexibly and globally • Use of project management tools • Review of development step meetings, bringing forward preparation for POC* exams
Pursue the possibility of early approval	• Promote biomarker search from early stage　• Efforts to reach consensus with authorities
Improved probability of success	• Robust clinical study planning　• Strengthening of POC exams planning • Prioritization of clinical trial projects　• Consider partnering after obtaining POC • Thoroughness of timing of study planning • Establishment of a system to promote health technology assessment (HTA) and clinical development in parallel

* Proof of Concept (POC): Demonstrating the efficacy of a drug under development.

(3) Promoting human capital management that allows each employee to grow and diverse human resources to play an active role

The volume of operations is forecast to increase as we expand globally. Aiming to become a small but unique team, we will draw out the potential of each individual as much as possible and move forward with acquiring and developing human resources to support our global expansion and reforming our organizational culture.

(4) Business process reengineering and productivity improvement by promoting digitalization

Since digital technology is advancing rapidly, we proactively invest in digital systems and human resource development to take advantage of those advances.

We work to speed up and improve the efficiency of operations by tackling issues that arise in R&D and sales promotion activities through a data-driven response. In addition, because it is necessary to increase operational efficiency and productivity to continue to generate profit as we expand globally, we are moving forward with company-wide transformation through the promotion of DX topics that the management team are also involved in.

Having defined "human resources for business process reengineering (BPR)" as human resources who can fundamentally reform operations and create new businesses by discovering issues through the use of digital technology, knowledge, and business skills, we aim to have 10% of employees human resources for BPR by FY2028.

(5) Financial strategy for sustainable growth

Our basic policy on capital allocation is to actively make investments necessary for sustainable growth while ensuring financial soundness.

We plan to spend ¥190.0 billion over five years on R&D investments; ¥38.0 billion on capital investments, which includes constructing a new research building at the Drug Discovery Research Institute to respond to new technologies and generate innovation in drug discovery research; up to ¥100.0 billion for such purposes as investments for growth, including M&As and in-licensing, and acquisition of treasury stock, with the actual allocation flexibly being decided; and ¥42.0 billion on shareholder return. We will move forward with investments for growth while ensuring financial soundness, which includes unwinding cross-shareholdings and borrowing funds when necessary.