

Value Creation Process

Nippon Shinyaku's business responds flexibly to changes in society while leveraging diverse resources and strengths. This helps us provide our unique value of "Helping People Lead Healthier, Happier Lives."

Business Philosophy

Helping People Lead Healthier, Happier Lives

The External Environment Surrounding the Pharmaceutical Industry

- R&D advancement
- Prolonging healthy lives through breakthroughs in medical care
- Improving access to medical care
- Diversification of work styles

Material Issues

> P.22



Realizing a healthy future by creating innovation



Developing diverse human resources and realizing employee well-being



Resolving social issues and coexisting with the community



Strengthening efforts to protect the global environment



Strengthening governance

Inputs

> P.24



Human capital

Number of employees (consolidated): **2,243**

Investments in human resource development per employee: **¥93,000**



Social and relationship capital

Number of joint research and subcontracted research projects: **36**

Number of partner companies: **In-licensing, 19; out-licensing, 10**



Financial capital

Total consolidated assets: **¥283.6 billion**

Equity ratio: **87.1%**



Intellectual capital

R&D investment: **¥34.3 billion**

Patents held: **951 patents**



Manufacturing capital

Amount of capital investment: **¥31.0 billion**

Nucleic acid API purification plant at the Odawara Central Factory
Clinical trial API manufacturing facility



Environmental capital

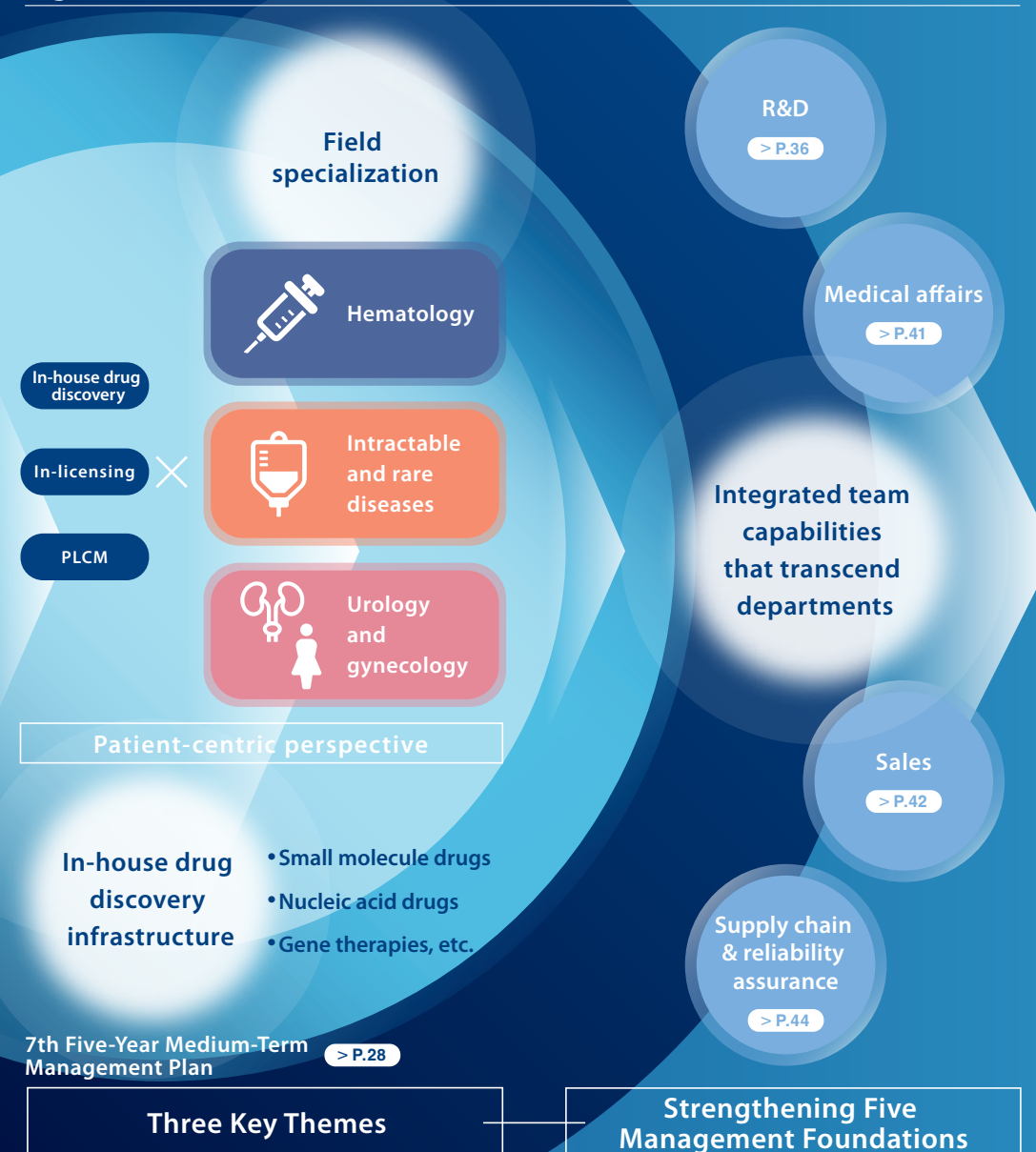
Energy consumption (electricity): **20,848,000 kWh**

Water consumption (tap water + well water): **177,000 m³**

Business Model

Pursuing originality on a global scale

Providing the world with quality pharmaceutical products and services to address diseases with unmet treatment needs



Outputs (Pharmaceuticals Business)

- High-quality, unique products that provide hope for patients suffering from illnesses
- **Uptravi**, for pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension
- **Viltepso**, for Duchenne muscular dystrophy
- **Vyxeos**, for high-risk acute myeloid leukemia
- Sherpa support program for patients with pulmonary hypertension
- Viltepso provision program in unapproved countries

Outcomes

- **Patients, consumers, medical professionals**
- Reducing symptoms and the burden of care, and enabling lifestyles that support both mental and physical health
- **Shareholders**
- Maximizing shareholder value through sustainable profit growth and improved capital efficiency
- **Employees**
- A workplace that provides not just high ease of working, but where employees can experience worthwhile work and a worthwhile life
- **Society (local communities, business partners, etc.)**
- Building trust from local communities and sustainable relationships with business partners
- **Environment**
- Realizing a sustainable society in balance with the environment

Creating various types of new "ways of life" for each person

Risks and Opportunities, Material Issues

○: Progressing on schedule △: Slightly delayed ×: Delayed

		Material issues	Indicators/KPIs for the final year of the 7th Medium-Term Management Plan (FY2028)		FY2024 KPI results	Progress
Risks	Lower value of existing therapies from emerging treatments/approaches based on new technology Scaling down Japan-focused business due to Japan's declining population More intense natural disasters, more diverse business risks Impact of loss of end-user trust on business activities	 Realizing a healthy future by creating innovation > P.36 > P.46 > P.54	Drug launches: 2 or more items/year	Launched a total of four items: Vyxeos, Jaypirca, Yuvanci, Upravi for children	○	
			Drug in-licensed: 1 or more items/year	Entered agreements for four items	○	
			New product launches of sports and aging care supplements: 10 items/5 years	Launched a total of three items: WEIGHT BURNER PREMIUM, Pre-Workout supplement, Multiple Vitamin Mineral	○	
			Planning of clinical trials based on patient centricity	Number of consultations with patient organizations, etc.: 10 in total	○	
Opportunities	Creation of novel therapeutic agents using new technologies Higher demand for health-related products as focus shifts from treatment to prevention Discovery of unmet needs based on a patient-centric perspective	Unique products originating from our aim to be a global healthcare company from Kyoto Creation of services and patient support based on patient centricity	Using safety information from PMS (post-manufacture and marketing surveys)	Completed Gazyva-specific post-marketing surveillance	○	
			Sales of key products (including products in development) (Upravi, Vilepso, NS-089, NS-050, NS-051, Fintepla, Vyxeos, Jaypirca, Gazyva, Defitelio, NS-401)	Total sales in Japan: ¥35.0 billion	○	
			Studying, surveying, and building systems that can handle regulations, focusing on Europe	Progressing according to plan	○	
			Stable supply of Nucleic Acid Drugs	Achieved stable supply of Vilepso, focusing on Japan and the U.S.	○	
Risks	Loss of personnel Reduced motivation due to lack of psychological safety	 Developing diverse human resources and realizing employee well-being > P.50	Annual training hours: 100 hours or more per person	Training hours per employee: 34.1 hours	×	
			Female manager ratio: 17% or more	Female manager ratio: 14.4%	○	
			PRIDE Index: Acquisition of Gold certification	PRIDE Index: Acquired Silver certification	○	
			Positive response rate for 3 items in engagement survey: 75% or more for each (1) I get a sense of personal achievement through work (2) I would recommend this company to other people as a great workplace (3) I want to contribute to this company in ways that go beyond just doing my work	Positive response rate for each item: (1) 72% (2) 63% (3) 70%	○	
Opportunities	Maintenance of employee health, diversification of human resources and work styles, and promotion of productivity and innovation by developing human resources A desirable place where people enjoy working	Achieving the “NS Mind” will result in the growth of each employee and build a resilient organization for business activities Achieving well-being and promoting DE&I	Writing and submitting papers after completion of Defitelio, Upravi post-marketing surveillance	Surveillance underway	—	
			Number of researchers receiving grant: 100 people/5 years	Number of grant receivers: 20	○	
			Human rights policy understanding rate among all employees: 100%	Conducted training for all employees, including Group employees	○	
			Number of books lent by Sparkling Future Mobile Library: 25,000 books/5 years	Number of books lent by Sparkling Future Mobile Library: 5,724 books	○	
Risks	Loss of business opportunities due to delays in addressing healthcare disparities Loss of trust, and impact on business due to the occurrence of human rights issues	 Resolving social issues and coexisting with the community > P.56	Number of visitors to tours of Yamashina Botanical Research Institute	Number of visitors to Yamashina Botanical Research Institute: 2,223	○	
			Implementing social contribution activities rooted in Kyoto	Futaba Aoi offering: 200 stocks Donation of rice to Children's Cafeterias charity: 300 kg	○	
			Climate change countermeasures	Scope 1+2 emissions: 9,333 t-CO ₂	△	
			Promoting resource circulation	Water resource intensity: 99 m ³ /100 million yen Recycling rate of waste plastics: 90%	○	
Opportunities	Reduced CO ₂ emissions and facility operating costs due to climate change actions	 Strengthening efforts to protect the global environment > P.58	New product launch of preservatives: 1 item/year	Launched Maikohan RB-1 (Rice enzyme preparation)	○	
			ROIC: 9% or more	ROIC: 17.0%	○	
			Corporate Governance Code compliance: 100%	Compliance: 100%	○	
			Number of law or regulation violations with major impact on business	Number of law or regulation violations: 0	○	
Risks	Increased international legal compliance. Corruption due to reduced awareness of integrity and compliance Erosion of trust and brand value from cyberattacks, data leaks or other information security issues Decrease in credibility among stakeholders due to inappropriate responses	 Strengthening governance > P.66	Increase in number of IR meetings with directors	Number of meetings: 93	○	
			Maintain and improve external evaluation agency scores	CDP score for climate change: A- CDP score for water: A-	○	

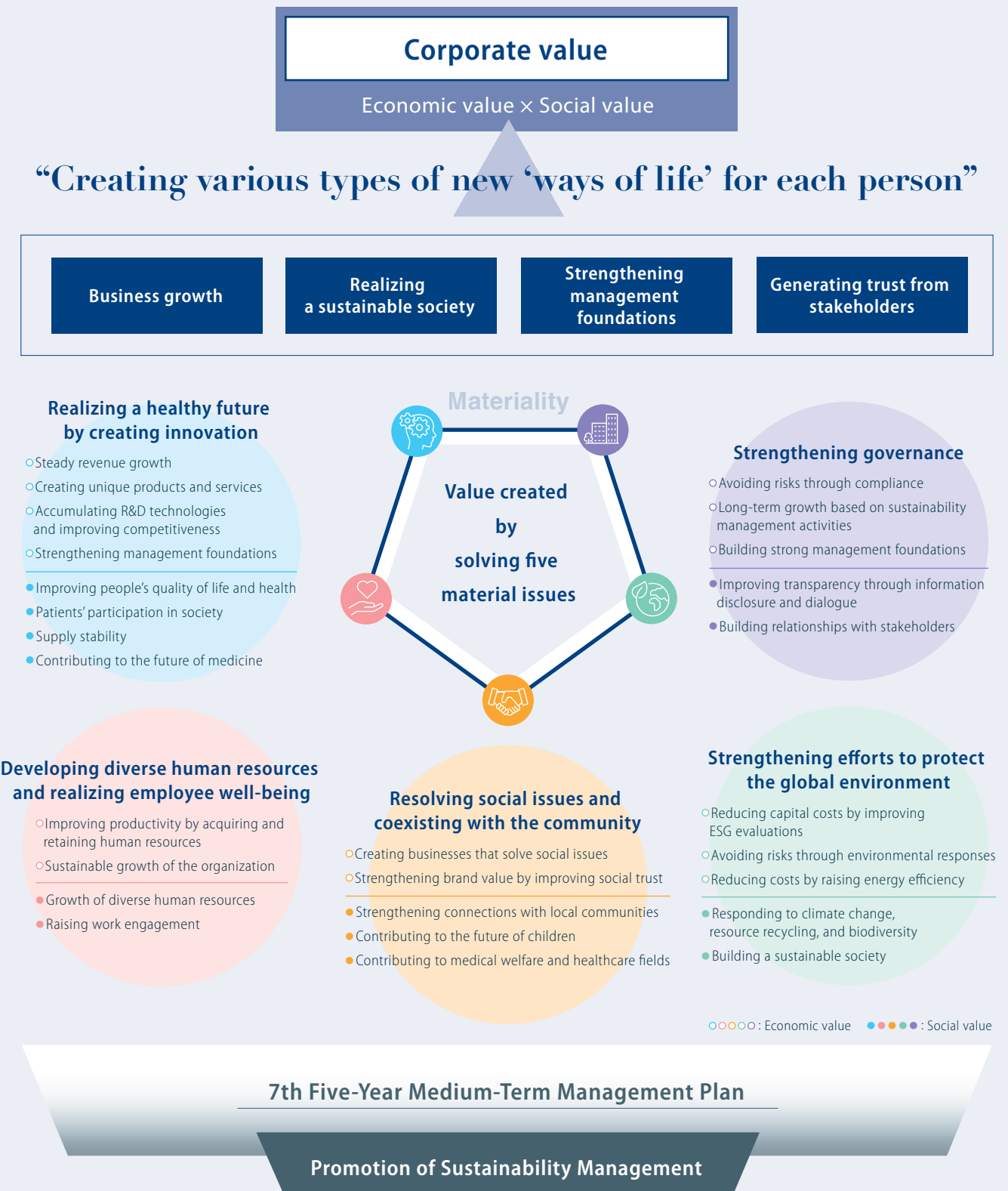
Management Capital

The Nippon Shinyaku Group creates sustainable value using the capital we hold in the form of human resources and intellectual property and the capital provided by all outside stakeholders, including medical professionals and suppliers.

	Characteristics and results	Future direction of capital
 Human capital	- Number of employees (consolidated): 2,243 - Overseas employee ratio: 6.5% - Hours of voluntary training received per employee: 18.8 hours - Number of NS Academy enrollees Excluding repeaters: 1,571 - Total: 4,460	The driving force of sustainable growth is human resources. We are promoting human capital management with the aim of becoming a company employees choose. To create an organizational climate where all individuals give their all when taking on challenges, we started to tackle the following four issues: realizing employee treatment in line with roles, duties, and accomplishments; realizing self-directed career development and placing of the right employee in the right position; realizing a highly psychologically safe organization; and realizing flexible work styles.
 Social and relationship capital	- Number of joint research and subcontracted research projects: 36 - Number of partner companies: In-licensing, 19; out-licensing, 10 - Acceleration of R&D and sales activities - Collaboration with partner companies and medical professionals - Good relationships with local communities	By listening to the opinions of patients and their family members, we provide not only the treatments but also the support that they need. We will grow sustainably and provide value by collaborating with partner companies and medical professionals to gain the trust of society. Also, we will expand the development pipeline (make it multi-pronged) through partnerships with academia and venture companies, with the aim of creating new therapeutic technologies that combine Nippon Shinyaku's strengths with cutting-edge technologies.
 Financial capital	- Total consolidated equity: ¥247.3 billion - Total consolidated assets: ¥283.6 billion	To continuously create unique, high-quality pharmaceuticals for patients with unmet treatment needs, we are making strategic investments in R&D while remaining conscious of our capital structure and cost of capital in order to expand our development pipeline (make it multi-pronged). With an emphasis on the stable supply of pharmaceutical products and functional food to medical professionals, patients, and other stakeholders, we will make the necessary investments while ensuring that we have working capital.
 Intellectual capital	- Pharmaceutical technologies (nucleic acid and small molecule) - R&D investment: ¥34.3 billion - Patents held: 951 patents - Pipeline focused on hematology, and intractable and rare disease fields - Specialized knowledge accumulated by focusing on specific fields	Intellectual property is essential for tackling the challenge of new modalities in drug discovery and globalization. To promote R&D, drug discovery, and global development in advance of other companies, we are reinforcing the advantages that our businesses offer and working to continue to improve corporate value through the protection and use of intellectual property in a long-term, multifaceted and strategic way.
 Manufacturing capital	- Amount of capital investment: ¥31.0 billion - Nucleic acid API purification plant at the Odawara Central Factory - Clinical trial API manufacturing facility	To continuously improve corporate value, we will make capital investments while remaining conscious of capital costs in order to expand and streamline production facilities and strengthen our R&D capabilities. With an eye toward expanding our business internationally, we will build a global supply chain system that meets the regulations of each country and do all that we can to provide patients worldwide with a stable supply of high-quality, unique pharmaceuticals.
 Environmental capital	- Energy consumption (electricity): 20,848,000 kWh - Water consumption (tap water + well water): 177,000 m³	The Nippon Shinyaku Group is reducing its environmental impact in all areas of its business activities based on a Basic Environmental Policy. We aim to realize a sustainable society by striving to protect, sustain, and improve the environment through eco-considerate business activities. We also recognize that natural resources are finite and strive to reduce the amounts of resources we use while also promoting resource recycling through the use of recycled resources.

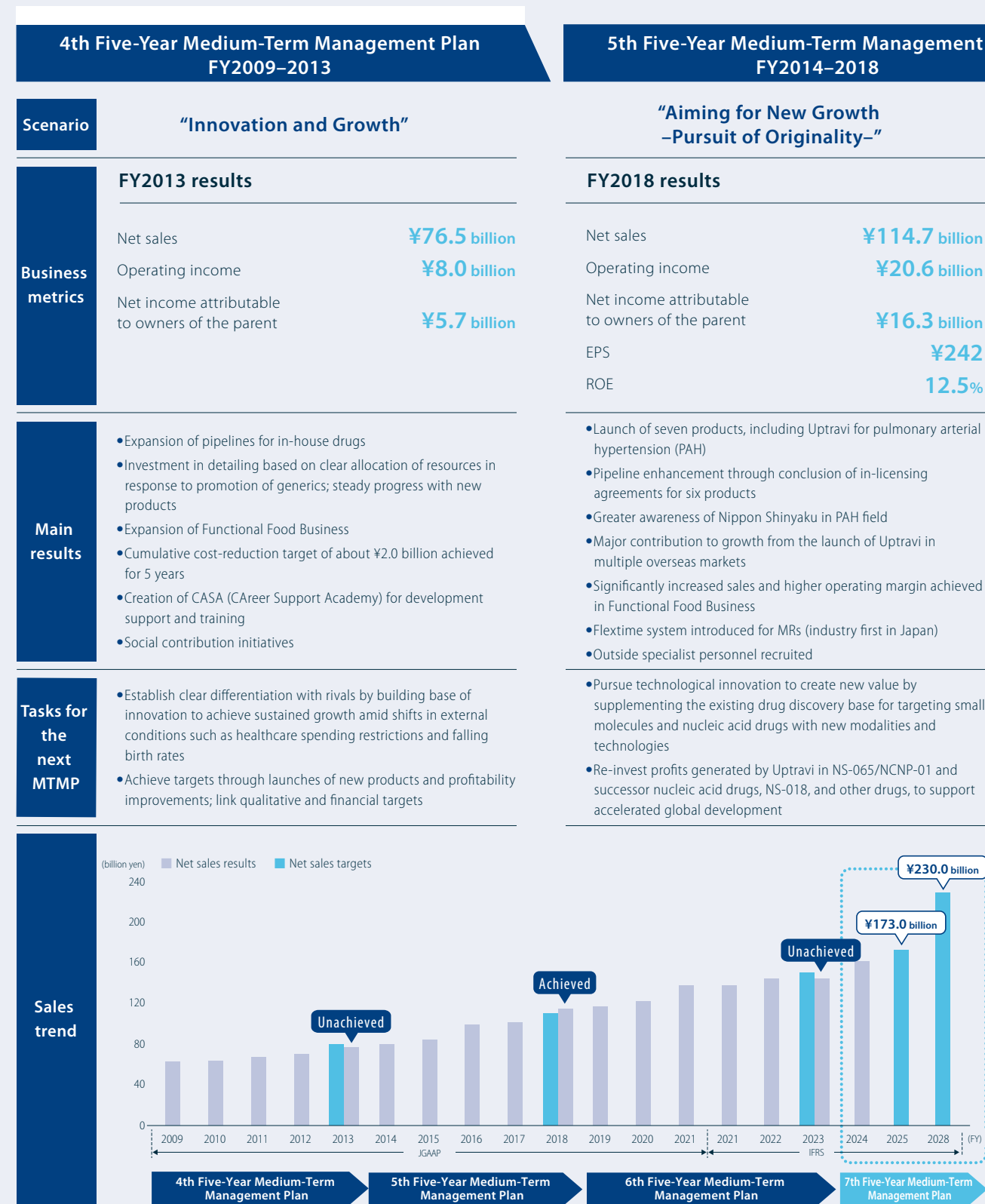
Material Issues and Their Relationship with Corporate Value

Implementing sustainability management while also addressing material issues that are linked to the 7th Medium-Term Management Plan will lead to improved corporate value. Resolving material issues will create diverse value in both the economic and social spheres, and we aim for the sustainable improvement of corporate value from four main perspectives.

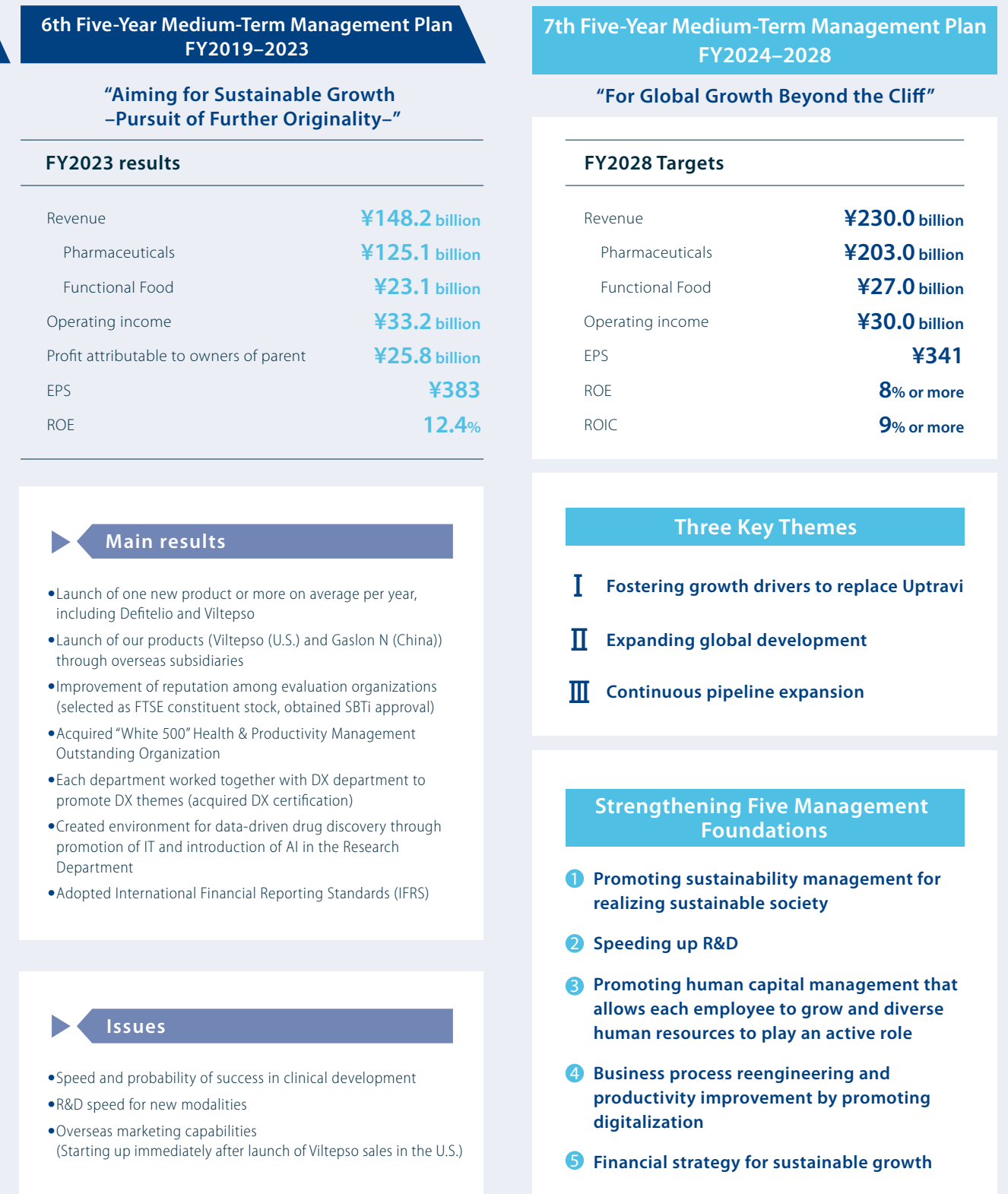


Medium-Term Management Plans Through the Years

Nippon Shinyaku constantly took on new challenges based on the 4th Five-Year Medium-Term Management Plan that was started in FY2009—under a business philosophy of “Helping People Lead Healthier, Happier Lives.” In the subsequent planning periods as well, we continuously launched new, innovative products into the market, resulting in our achievement of record highs in sales and all profit metrics in FY2023.



In the 7th Five-Year Medium-Term Management Plan, we will work to resolve the issues that came to light in the 6th Five-Year Medium-Term Management Plan and drive forward together as a company toward achieving our goals. In the future, we aim to continue to provide unique pharmaceutical products to patients around the world who have unmet treatment needs.



Medium-Term Management Plans Through the Years

7th Five-Year Medium-Term Management Plan Targets

In the 7th Five-Year Medium-Term Management Plan “For Global Growth Beyond the Cliff,” which started in FY2024, we will engage in “Three key themes” and in “Strengthening five management foundations” to overcome Uptravi’s patent cliff and achieve sustainable growth. In FY2024, we launched four new products, including Vyxeos, and entered into licensing agreements for four more products. We are also actively promoting global expansion through measures such as strengthening our marketing system in the U.S. and considering business expansion into Europe. As a result of these initiatives, we aim to achieve revenue of ¥230.0 billion and operating income of ¥30.0 billion by the final year of the 7th Medium-Term Management Plan in FY2028, and revenue of ¥300.0 billion and operating income of ¥50.0 billion by FY2030.

Revenue

230.0 billion yen

Operating profit

30.0 billion yen

ROIC

9% or more

EPS

341 yen

ROE

8% or more

Pharmaceutical Business Segment Targets

FY2028

Revenue

¥203.0 billion

Operating profit

¥28.2 billion

ROIC

9% or more

Functional Food Business Segment Targets

FY2028

Revenue

¥27.0 billion

Operating profit

¥1.8 billion

ROIC

9% or more

Three Key Themes		
I Fostering growth drivers to replace Uptravi We launched Vyxeos and Jaypirca, treatments for hematological malignancy, and Yuvanci, a treatment for pulmonary arterial hypertension (PAH), as growth drivers during the 7th Medium-Term Management Plan. In terms of PLCM, we obtained a pediatric indication for the Uptravi PAH treatment and we started sales of a pediatric formulation. We will accelerate the market penetration of these new products through omni-channel strategies that leverage the MR channel and digital channel.	II Expanding global development At our U.S. subsidiary NS Pharma, we are preparing for the U.S. launch of RGX-121, which will be the Nippon Shinyaku Group's first gene therapy drug, and of the cell therapy product CAP-1002, thereby working to expand our global product lineup. In Europe as well, we are considering all potential strategies, including in-house marketing, alliances, and M&A, to accelerate our global expansion.	III Continuous pipeline expansion We will continue to expand our pipeline, primarily through in-house drug discovery, in-licensing, and PLCM. For in-house drug discovery, we believe that the utilization of new drug discovery modalities, especially through open innovation, will become important, and we have entered into a research alliance with MiNA Therapeutics of the UK. For in-licensing, we have entered into licensing agreements for products such as RGX-121, RGX-111, ATSN-101, and Tadekinig alfa, and we aim in the future to continue to in-license at least one product per year.

Strengthening Five Management Foundations	
1 Promoting sustainability management for realizing sustainable society > P.56	While promoting sustainability management to realize a sustainable society, we work to solve five material issues. We established a new department dedicated to IR in FY2024 to strengthen information disclosure. We also held education activities and training for employees and subsidiaries to reduce the risk of human rights issues. We will set specific targets and take active measures to reduce greenhouse gas emissions, recycle waste plastics, and reduce water consumption.
2 Speeding up R&D > P.36	In drug discovery research, we aim to shorten the time from the drafting of a theme to the start of clinical study, and to build a system that enables us to launch at least one product a year. To do this, we are prioritizing projects, allocating management resources, and reviewing decision-making meetings. We are also trying to speed up the drug discovery research cycle by improving the drug discovery integrated database and introducing AI systems. In clinical development as well, we are promoting measures such as strengthening project management, reviewing clinical development processes, and making document creation more efficient through DX, with the aim of speeding up development.
3 Promoting human capital management that allows each employee to grow and diverse human resources to play an active role > P.50	We will implement human resource strategies that 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. As a part of acquiring and developing global human resources, we are reviewing our human resource development programs and recruitment plans, as well as promoting such initiatives as English language learning. We also recommend participation in exchange programs outside the company and internal pro bono work, and about 200 employees have taken part. Our LGBTQ initiatives are part of our efforts to realize a highly psychologically safe organization where employees recognize each others’ diverse values. These initiatives were recognized when we received Silver certification under “PRIDE Index 2024.”
4 Business process reengineering and productivity improvement by promoting digitalization > P.54	In R&D and sales promotion activities, we are identifying issues that can be sped up or made more efficient through DX and building systems in collaboration with the relevant departments. In terms of human resource development, “transformative talent” is defined as those who can identify issues and create fundamental business reforms or new businesses by utilizing DX and business skills, and we aim to have 10% of all employees certified as such talent by FY2028. To do this, we are encouraging employees to receive training via the DX learning video. By FY2024, 43% of all employees had been certified as human resources with basic DX knowledge.
5 Financial strategy for sustainable growth > P.30	Our basic policy on capital allocation is to actively make investments necessary for sustainable growth while ensuring financial soundness. At the initial formulation of the 7th Medium-Term Management Plan, we anticipated cash resources of 370 billion yen that combined operating cash flow before deduction of R&D expenses, cash on hand, and other items over five years, but the accelerated launch of new products means that we expect this amount to be exceeded. We plan to use the increased cash to invest in growth and distribute profits back to shareholders.