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

-For Global Growth Beyond the Cliff-

May 28, 2024

Nippon Shinyaku Co., LTD.
Toru Nakai
Representative Director, President

NIPPON SHINYAKU CO., LTD.

Agenda

- Review of the 6th Five-Year Medium-Term Management Plan
- Corporate Philosophy and Vision for 2035
- The 7th Five-Year Medium-Term Management Plan

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

The 6th Five-Year Medium-Term Management Plan

As "a company playing a meaningful role in the global healthcare sector", we took on the challenge of six actions to enhance our presence in the society.

Six Actions

1	**Creation of new value through R&D** Further enhancement of R&D capabilities Challenge for new drug modalities Launch of new products that meet market needs	results	(Pharmaceuticals) Launch at least one new product per year on average (Functional food) Continuous development of new products
		issues	(Pharmaceuticals) Speed and probability of success in clinical development research on new modalities
2	**Development of global business** Building an organizational structure suitable for global business development in all divisions	results	(Pharmaceuticals) Launch of Viltepso in the U.S. by our own marketing Launch of Gaslon N in China by our own marketing
		issues	(Pharmaceuticals) Marketing capabilities of Viltepso in the U.S.
3	**Increase in corporate value by strengthening ESG management** Strengthening ESG (Environmental, Social and Governance) management initiatives through business activities	results	Improvement of the recognition by external parties (Inclusion in ESG indices (FTSE), Approval by SBTi)
4	**Creation of organizational climate in which every employee can flourish** Providing opportunities for each employee to take on positive challenge and grow Respect diversity without distinction of gender, nationality, culture, etc.	results	Introducing various systems to create a comfortable working environment for diverse human resources Designation as a "White 500" Health & Productivity Management Outstanding Organization
5	**Active use of AI and adoption of IT** Improving productivity through active use of AI and RPA, etc.	results	Promoting DX themes by DX department and each department together based on our DX vision (Designated as Digital Transformation Certification) Introducing generative AI and data analysis AI to improve the environment
6	**Further strengthening of business foundation** High profitability of business, cost management, effective use of management resources and restructuring of management systems	results	Introducing a budget management system and promoting cost management to achieve a highly profitable and efficient management structure Disclosure accordance with International Financial Reporting Standards (IFRS)

Products Planned to Be Launched During the 6th Medium-Term Management Plan

Products planned to be launched by FY2023

In-house

- NS-065/NCNP-01 DMD **Viltepso** domestic and overseas (○)
- NS-089/NCNP-02 DMD domestic and overseas (△)
- NS-018 myelofibrosis overseas (×)

In-licensing

- NS-73 **Defitelio** domestic sinusoidal obstruction syndrome (treatment) (○)
- NS-73 domestic sinusoidal obstruction syndrome (prophylaxis) (×)
- NS-32 **MonoVer** domestic iron deficiency anemia (○)
- ZX008 **Fintepla** domestic rare intractable epilepsy (○)

PLCM

- NS-304 **Uptravi** domestic chronic thromboembolic pulmonary hypertension (○)
- NS-304 domestic arteriosclerosis obliterans (△)
- macitentan domestic chronic thromboembolic pulmonary hypertension (×)
- NS-17 **Vidaza** domestic AML (○)

Launched: **6** products

Terminated: **3** products

Delayed: **4** products

Products with delayed development schedules

- NS-050/NCNP-03 DMD domestic and overseas (△)
- NS-051/NCNP-04 DMD domestic and overseas (△)

○ Launch　△ Delay　× Termination

DMD : Duchenne Muscular Dystrophy
AML : Acute Myeloid Leukemia

Major Management Issues

❶Speed and success probability in clinical development

- Delay of start of the studies for NS-089/NCNP-02 and NS-050/NCNP-03
- Prolonged clinical trials and termination of development for NS-018
- Termination of the development for NS-161

❷R&D speed for new modalities

- The length of time for development of next-generation nucleic acid drugs and gene therapeutics

Major issues identified in the 6th Medium-Term Management Plan

❸Marketing capabilities overseas

- Delay of initial sales growth of Viltepso in the U.S.
- Struggling to increase market share 3 years after launch of Viltepso in the U.S.

During the 7th Medium-Term Management Plan, we will resolve issues identified in the 6th Medium-Term Management Plan.

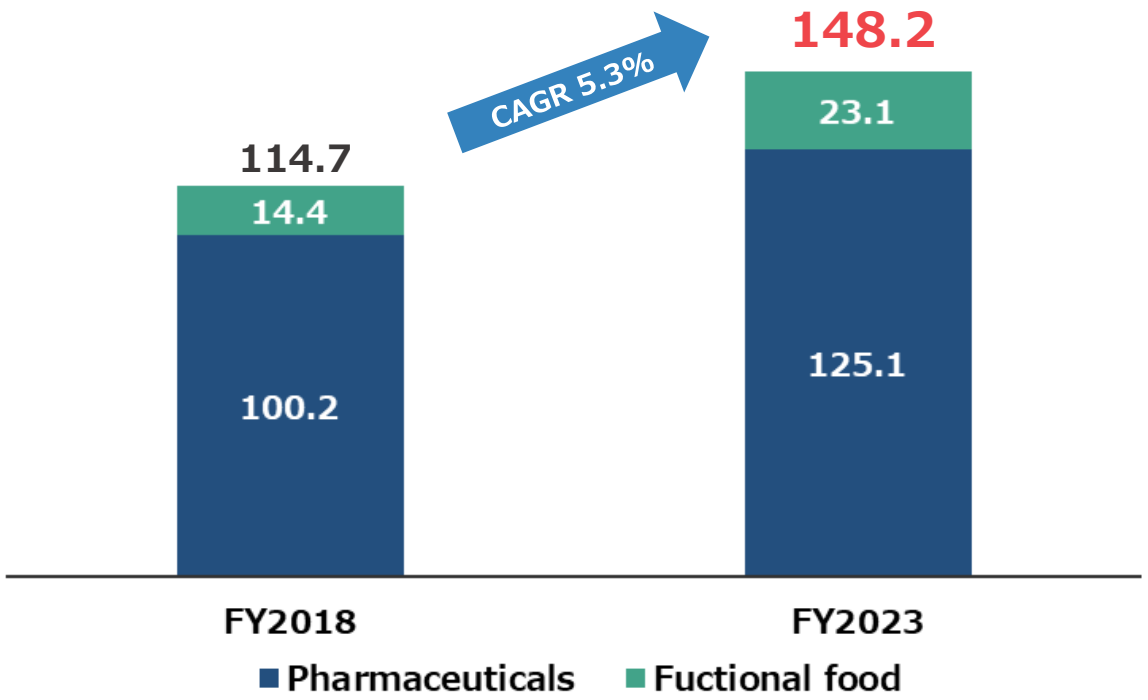
Targets of the 6th Medium-Term Management Plan

Among FY2023 targets in the plan, we have achieved functional food segment revenue an company ROE.

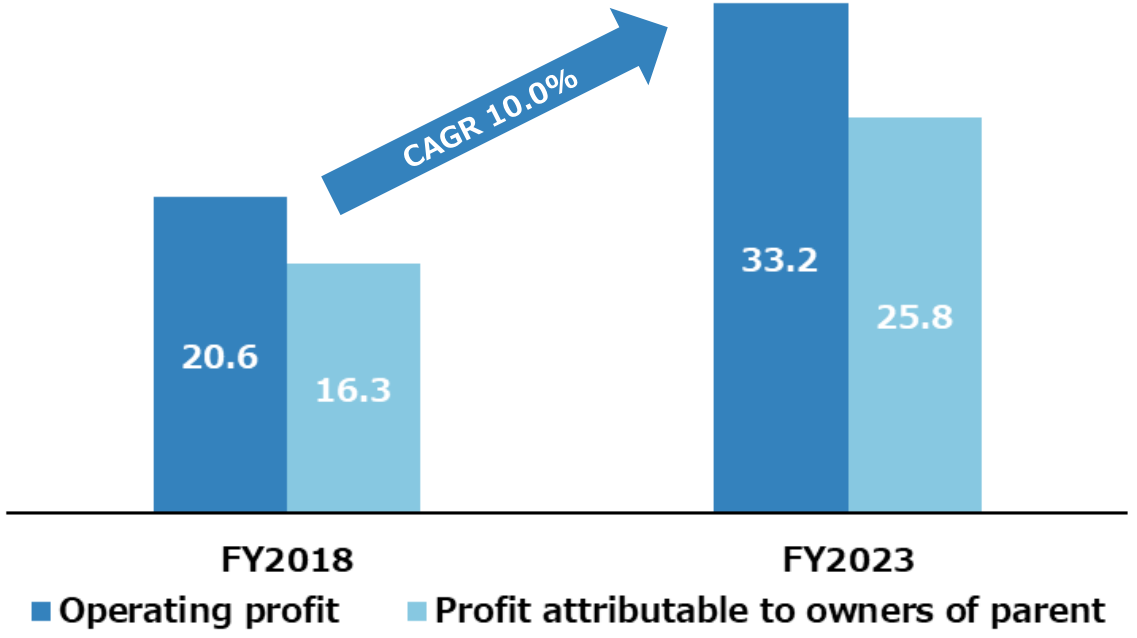
	Target in FY2023	Results in FY2023
Revenue	150 billion yen	148.2 billion yen
Pharmaceuticals	133 billion yen	125.1 billion yen
Functional Food	17 billion yen	23.1 billion yen
Operating profit	40 billion yen	33.2 billion yen
Profit attributable to owners of parent	30 billion yen	25.8 billion yen
EPS	445 yen	383 yen
ROE	10% or more	12.4%

In the 6th Medium-Term Management Plan, we established a foundation for global expansion through working on our own marketing in the U.S. and China, and achieved growth with record high revenue and respective profits.

Net Sales/Revenue (billions of yen)



Operating profit and profit attributable to owners of parent (billions of yen)



Corporate Philosophy and Vision for 2035

Environmental Recognition

External environment

<Global>

- Population growth
- Advancement of R&D
- Development of AI and digital technology
- Climate change
- Increase in natural disasters
- Increased geopolitical risk
- Diversification of values

<Japan>

- Declining birthrate and aging population
- Population decline
- Promotion of generic products
- Annual NHI price revision
- Drag lag and drug losses

Internal environment

<Nippon Shinyaku>

- Management issues from The 6th Medium-Term Management Plan
- Uptravi's patent cliff
- Increase in R&D expenses

Important initiatives for Nippon Shinyaku

- **In a drastically changing business environment, we see not only Japan but also the global market as a growth market.**
- **We will respond quickly to technological evolution with an enterprising spirit.**
- **We will provide products and services that meet the diversifying needs of people's lives.**

A global healthcare company from Kyoto creating various types of new ways of life for each person around the world

Today, when the environment is changing rapidly and the future is uncertain, what is needed is a discovery for a new form of happiness and a new way of life.

Nippon Shinyaku has a strong belief in creating a world where all people can live happily.
Nippon Shinyaku has always been serious about one's life and has boldly taken on unprecedented and difficult challenges.
Nippon Shinyaku inherits the venture spirit of pioneering the future with an enterprising spirit rooted in Kyoto.

That is why Nippon Shinyaku will help create a new world in the future.

In this time when there are various ways of thinking and life,
all of our employees think about one's life together and we will provide values to the world without being bound by existing products and frameworks.
By doing this, we aim to contribute to the life of people around the world.

Realization of Management Philosophy and Vision for 2035

In two business segments of pharmaceuticals and functional food, we will differentiate ourselves from competitors and achieve continuous new product launches globally. Through these initiatives, we aim to resolve issues of materiality and achieve Vision for 2035 “A global healthcare company from Kyoto creating various types of new ways of life for each person around the world”.

There are as many ways of life as people

Pharmaceuticals

Functional food

With thinking lives of all people based on patient centricity and client perspective, we will create a new way of life by products or services based on two business segments, pharmaceuticals and functional food, and contribute to help people lead healthier, happier lives.

Toward the Realization Vision for 2035

Toward realizing Vision for 2035, we aim to resolve issues of materiality by integrating management policy and sustainability policy in our operations.

Management Policy

Basic Policies to achieve Vision for 2035

- Supply Unique and High-quality Products and Services (customers)
- Earn the Trust of Society (society)
- Develop Each Employee (employees)

Sustainability Policy

Policies to clarify our stance on promoting sustainability management

Recognizing responses to environment and social issues as material in our management, Nippon Shinyaku Group aims to realize a sustainable society. To fulfill this aim, the Group conducts educational and awareness-raising activities intended for all employees to further develop conscious of sustainability among them.

Materiality

①Realizing a healthy future by creating innovation
②Developing diverse human resources and realizing employee well-being
③Resolving social issues and coaxing with the community
④Strengthening efforts to protect the global environment
⑤Strengthening governance

Vision for 2035

A global healthcare company from Kyoto creating various types of new ways of life for each person around the world

In March 2023, we revised the issues of materiality due to drastic changes in our business environment

Changes in the business environment

- Increase in R&D expenses
- Uptravi's patent cliff
- Declining birthrate and aging population
- Promotion of the generic products
- Development of AI and digital technology
- Advancement of R&D
- Natural disasters
- Annual NHI price revision

Overview of Management

Management Philosophy

Values and decision criteria for our business

Helping People Lead Healthier, Happier Lives

Slogan

A catchy phrase for the management philosophy

A new way of life

Vision for 2035

A shareable vision of how to provide our value to society over a specific long-term period of time and how to increase corporate value sustainably over the long term

A global healthcare company from Kyoto creating various types of new ways of life for each person around the world

Management Policy

Basic Policies for realizing Vision for 2035

・Supply Unique and High-quality Products and Services (customers) ・Earn the Trust of Society (society)
・Develop Each Employee (employees)

Sustainability Policy

Policies to clarify our stance of promoting sustainability management

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NS Mind

Attitude and awareness that all employees aim for

・Give your all for yourself ・Give your all for others ・Give your all for society

Guidelines for action

Guiding for the work process

・Challenge ・Speed ・Investigation ・Smile

Issues of materiality

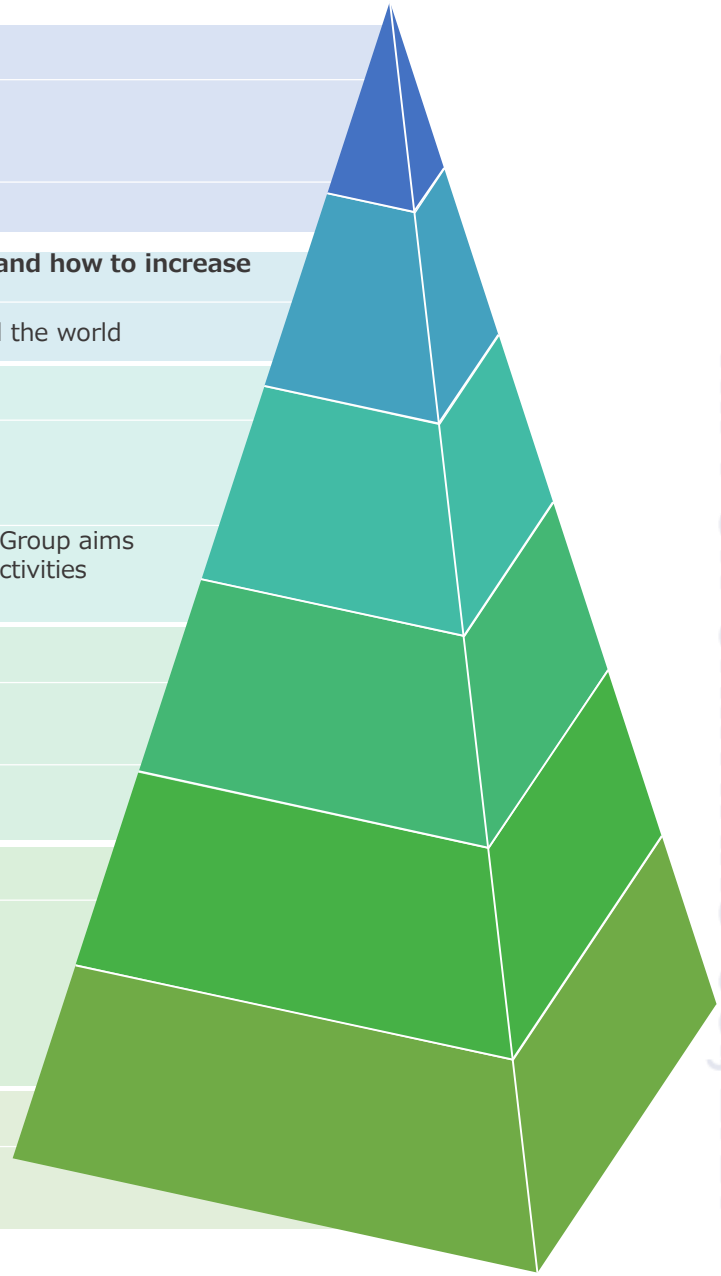
Material issues for sustainable growth with society

・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

Management plan

Scenario for growing toward Vision for 2035

The 7th Five-Year Medium-Term Management Plan (FY2024-FY2028)
“For Global Growth Beyond the Cliff”

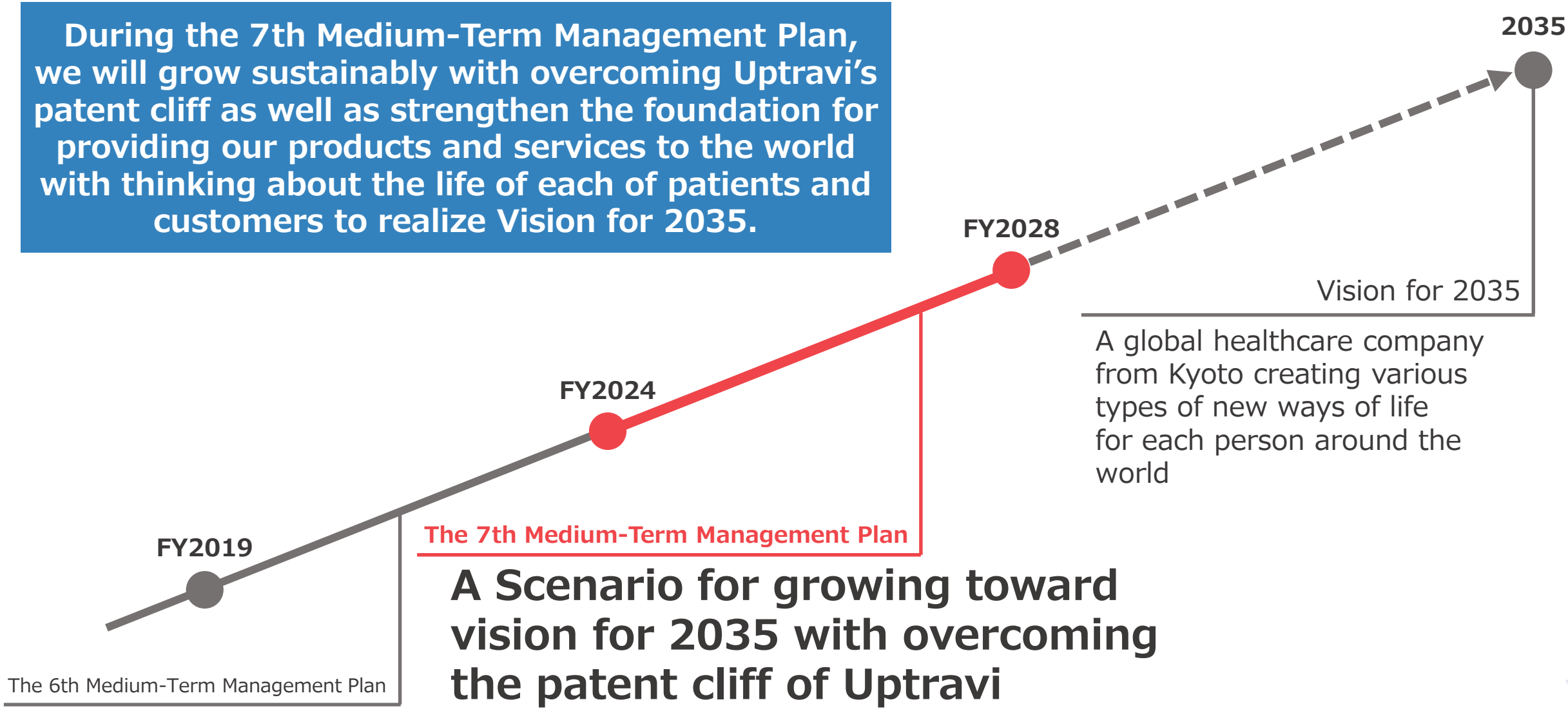


The 7th Five-Year Medium-Term Management Plan

-For Global Growth Beyond the Cliff-

Positioning of the 7th Medium-Term Management Plan

During the 7th Medium-Term Management Plan, we will grow sustainably with overcoming Uptravi's patent cliff as well as strengthen the foundation for providing our products and services to the world with thinking about the life of each of patients and customers to realize Vision for 2035.



A Scenario for growing toward vision for 2035 with overcoming the patent cliff of Uptravi

Establishing a Foundation for Growth Overcoming the Patent Cliff

The patent of Uptravi, which has supported Nippon Shinyaku's growth, will expire in FY2027, and royalty revenue, which accounts for the majority of revenues from the licensing of industrial property rights, are expected to decline significantly.
During the 7th Medium-Term Management Plan, we will focus on overcoming Uptravi's patent cliff by prior investment for future growth and establishing a revenue base that is not dependent on royalty revenue.

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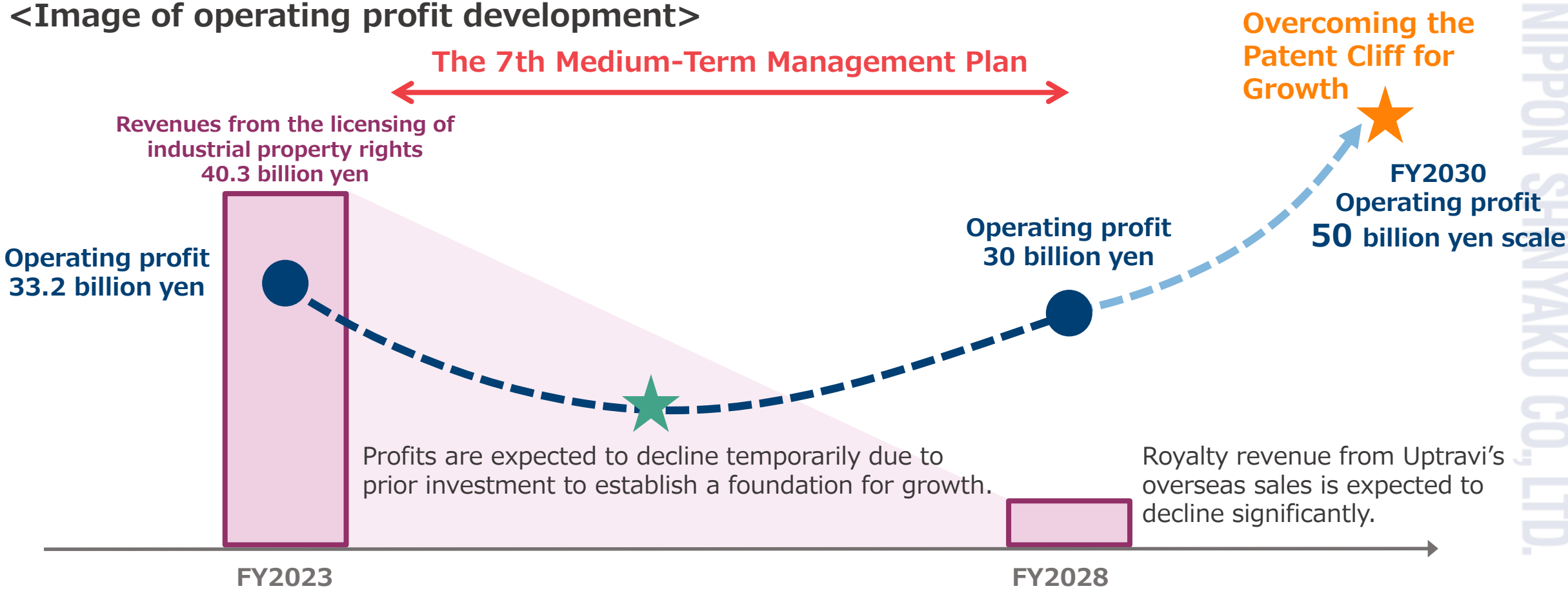
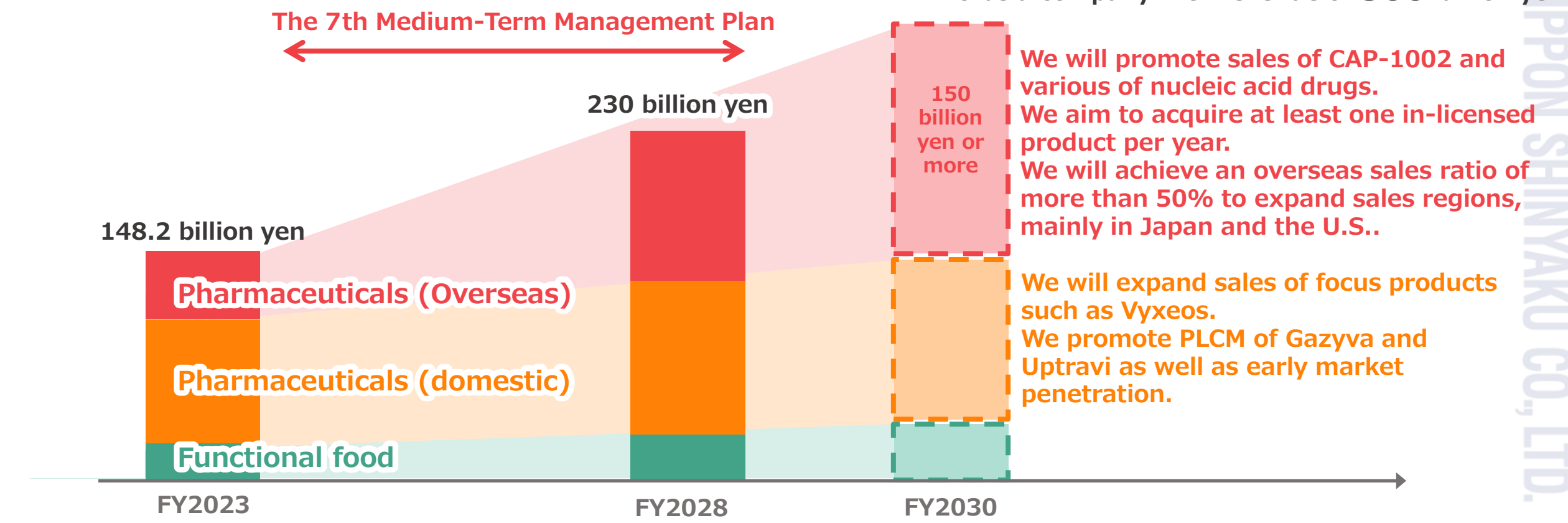


Establishing a foundation for growth overcoming the patent cliff

We plan to achieve revenues of 300 billion yen in FY2030 by promoting investment in R&D pipeline, in-licensed products, M&A, etc. during the 7th Medium-Term Management Plan period.

< Image of revenue development >



We will promote sales of CAP-1002 and various of nucleic acid drugs.
We aim to acquire at least one in-licensed product per year.
We will achieve an overseas sales ratio of more than 50% to expand sales regions, mainly in Japan and the U.S..

We will expand sales of focus products such as Vyxeos.
We promote PLCM of Gazyva and Uptravi as well as early market penetration.

Overview of the 7th Medium-Term Management Plan

During the 7th Medium-Term Management Plan, we will promote "three key themes and strengthening five management foundations" to realize Vision for 2035. In each of the Pharmaceuticals and Functional Food segments, we will thoroughly allocate management resources and reduce costs by prioritizing them based on business strategies, and manage the capital efficiency of each segments by ROIC* to secure earnings that exceed the cost of capital.

*ROIC (%) = Operating profit after tax / Invested capital (Non-current assets + Net working capital)

Targets in FY2028

Revenue 230 billion yen

Operating profit 30 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 sustainable 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

Our Business Strategies

Business Strategy for Pharmaceutical Segment

Business Strategy

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**
  Focusing 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**
  Focused as much as in-house drug discovery
- **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 in each region and increase market share

Pharmaceutical Business Segment Targets

	FY2028
Revenue	203 billion yen
Operating profit	28.2 billion yen
ROIC	≧ 9%

Business Strategy for Functional Food Segment

Business Strategy

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

- **B to B Business** — Focus on preservatives, for which demand is expected to increase due to the focus on reducing food loss
- **B to C Business** — Further accelerate growth of sports supplement「WINZONE Whey Protein」
  Enhance lineup of anti-aging care supplements by developing new products
- **Overseas Expansion** — Developing initiatives and systems for business development in Asian countries and other overseas markets

Functional Food Business Segment Targets

	FY2028
Revenue	27 billion yen
Operating profit	1.8 billion yen
ROIC	≧ 9%

Three Key Themes

Three Key Themes

I. Fostering growth drivers to replace Uptravi

As growth drivers during the 7th Medium-Term Management Plan, we will launch various DMD products globally (CAP-1002, NS-089/NCNP-02, NS-050/NCNP-03, NS-051/NCNP-04), new hematologic cancer products in Japan (Vyxeos, pirtobrutinib, NS-401) and lifecycle management of approval drug products (PLCM) (Gazyva for renal disease, Fintepla, Uptravi for pediatric and high-dose formulations) and achieve early market penetration.

II. Expanding global development

In the U.S. and China, where we have already run by our own marketing, we will strengthen the product line-up.
We will expand marketing areas to Europe such as U.K., Germany and France, as well as other regions, by various means including M&A.

III. Continuous pipeline expansion

We will continue to expand our pipeline by in-licensing clinical trial stage products and strengthening in-house drug discovery through open innovation and AI drug discovery.

Key Theme I : Fostering Growth Drivers to Replace Uptravi

As growth drivers during the 7th Medium-Term Management Plan, we will launch new products in the DMD group, the hematology group, and the PLCM group.

DMD

CAP-1002 : P3 in progress

NS-089/ NCNP-02 : P2 in progress

NS-050/ NCNP-03 : P1 in preparation

NS-051/ NCNP-04 : P1 in preparation

Hematology

Vyxeos : Launch
High-risk acute myeloid leukemia

LY3527727
Mantle cell lymphoma : Application
Chronic lymphocytic leukemia : P3 in progress

NS-401 : P1/2 in progress
Blastic plasmacytoid dendritic cell neoplasm

PLCM

Uptravi : Under application
Pediatric pulmonary arterial hypertension

Fintepla : P3 in progress
CDKL5 gene deficiency

Gazyva : P3 in progress
Lupus nephritis
Pediatric nephrotic syndrome
SLE without nephropathy

Key Theme Ⅰ : Fostering Growth Drivers to Replace Uptravi

Within the period of this plan, we plan to launch an average of at least two new products per year.
We aim to acquire at least one in-licensed product each year.

We will conduct an additional P3 study of Viltepso and aim to launch it in Europe and China.

Target for launching new products

	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028
Domestic	NS-87 (VYXEOS) : high-risk AML※		NS-401 : BPDCN※	NS-089/NCNP-02 : DMD	NS-050/NCNP-03 : DMD
	LY3527727 (pirtobrutinib) : 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

※ high-risk AML: high-risk acute myeloid leukemia; MCL: mantle cell lymphoma; pediatric PAH: pediatric pulmonary arterial hypertension; BPDCN: blastic plasmacytoid dendritic cell tumor
The launch date for pirtobrutinib (LY3527727) for chronic lymphocytic leukemia has not been determined.

Key Theme Ⅰ : Fostering Growth Drivers to Replace Uptravi

Domestic Sales Strategy - Establish an organization that can act quickly and efficiently to achieve market penetration of a wide range of products. -

The areas of greatest focus are hematology, pulmonary hypertension, and pediatric neurology. When adding indications to existing products or launching new products, we will promote omni-channel activities utilizing MR and digital channels, with the highest priority on early start-up.

Hematology

Vyxeos and pirtobrutinib are scheduled to be launched in FY2024, and NS-401 in FY2026.
(Existing products: Gazyva, Defitelio, Vidaza, Trisenox, Amnolake, Cylocide)
Establish a position as the No. 1 pharmaceutical company in the field while maximizing each product.

Pulmonary Hypertension

Addition of pediatric indication for Uptravi in FY2024. And expansion of the lineup thereafter in addition to existing Uptravi, Opsumit, and Adcirca. Establish the positioning of each drug with a focus on Uptravi, and maximize overall PH treatment products as the No. 1 pharmaceutical company in the field.

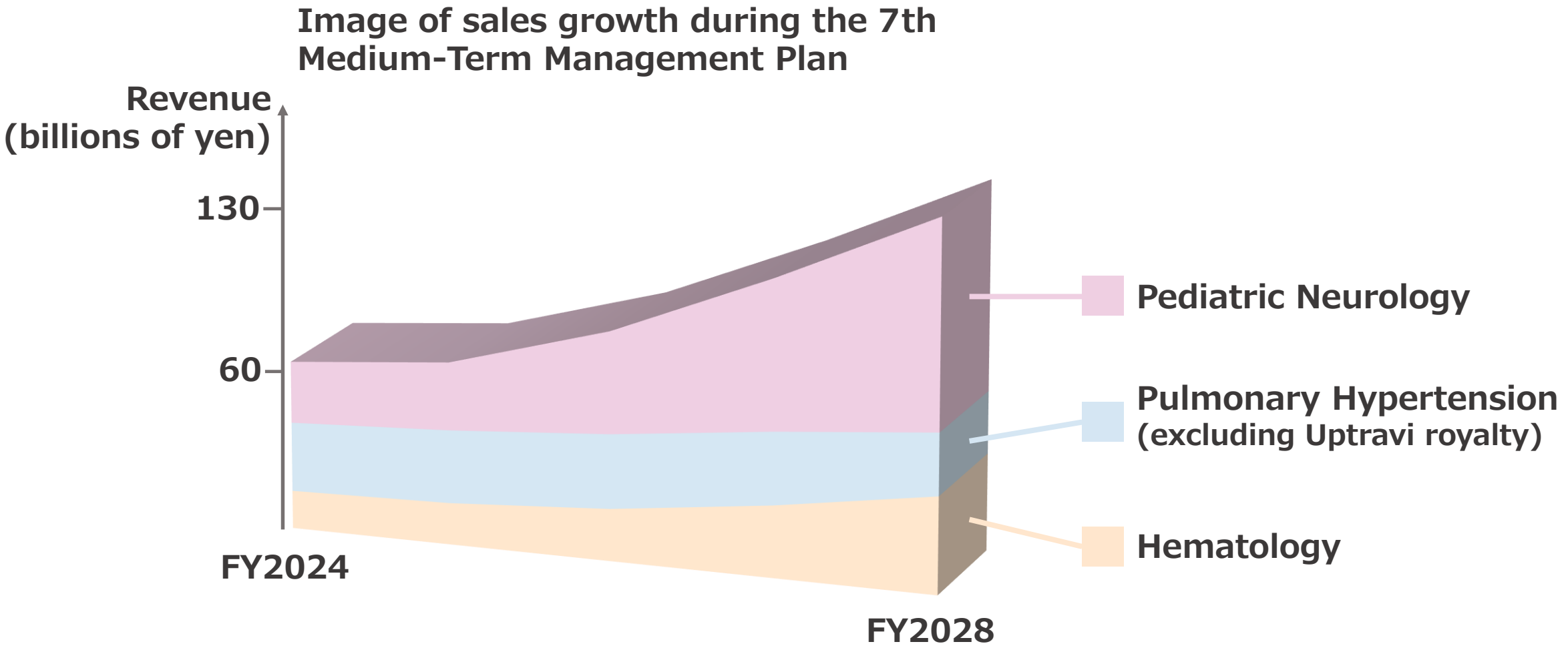
Pediatric Neurology

Epilepsy: In March 2024, Fintepla received an additional indication for Lennox-Gastaut syndrome. Deliver Fintepla to patients with Dravet and Lennox-Gastaut syndrome as soon as possible and develop it into a much-needed drug.

DMD: Viltepso's activities have led to the identification of DMD patient concentration facilities, and medical coordination from non-specialized facilities to DMD concentration facilities has also been established. These medical coordination schemes will be utilized for future products to be launched to deliver treatment as soon as possible.

Key Theme Ⅰ : Fostering Growth Drivers to Replace Uptravi

Global revenue of three focus areas in FY2028⇒ Aiming for over 130 billion yen



Growth Strategies for Overseas Subsidiaries

U.S. subsidiary (NS Pharma, Inc.)

In addition to Viltepso, other DMD investigational drugs (CAP-1002, NS-089/NCNP-02, NS-050/NCNP-03, NS-051/NCNP-04) to be launched

- Increase sales quickly, marketing efficiently
- Expand sales structure (HUB service, Patient support, market access)
- Expand advocacy activities ⇒ Create an environment where patients and their families can continue treatment with peace of mind
- Expand medical activities ⇒ Penetrate a novel cell therapy

China subsidiaries (Beijing Nippon Shinyaku Co., Ltd.; Tianjin Nippon Shinyaku Co., Ltd.)

Development and establishment of a marketing system for Viltepso and functional food in China

Key Theme II : Expanding Global Development

Further global expansion, establishment of optimal supply chain

- Promote global expansion by in-house sales, alliances, and M&A in order to provide Viltepso and other development products in the pipeline to patients around the world.
- In the U.S. and China, maximize the value of the existing products as well as promote licensing activities to expand our business with sales of in-licensed products.
- Strengthen group collaboration among R&D, clinical development, manufacturing, quality assurance, and overseas subsidiaries to promote smooth global expansion.

Business promotion for global growth

- Develop and implement a development policy for Europe
- Survey of global business development regions and business promotion
- Establishment of a global intellectual property system
- Global collaboration of business management departments

Global expansion on Reliability assurance system

- Consideration, investigation, and construction of a system that can comply with regulations in a wide range of marketing countries
- Establishment of a reliability assurance system that supports new modalities

Develop and strengthen global supply chain

- Reducing procurement costs and implementing sustainable procurement
- Increase in the value of the Odawara central factory
  - Production start-up of the nucleic acid API purification plant
  - Revitalization of existing plants
- Expansion of a global supply chain system
- Establishment of global cold chain

Key Theme III : Continuous Pipeline Expansion

Licensing in products in the clinical stage and strengthen in-house drug discovery by leveraging open innovation and AI drug discovery system to continuously expand the pipeline.

In-house drug discovery

- Promotion of nucleic acid drug discovery
  - DMD
  - Central nervous system
- Promote small molecule drug discovery
  - Hematology
  - Intractable/rare diseases
  - Urology and Gynecology

×

New / Outside Technology

- Utilization of open innovation and new drug discovery modalities
- Promote research and development using AI

Continuous Pipeline Expansion

In-licensing

- Activities with attention to priority
- Strengthening negotiation capabilities
- Acquire more than 1 item every year

PLCM

- Consider clinical trials for secondary indications simultaneously to maximize the value of the product

Promotion of Nucleic Acid Drug Discovery

Nucleic acid drugs act on genetic information

・Able to act on previously unapproachable targets
・Enables treatment of the root cause

- **Work on development of nucleic acid drugs for disease of the central nervous system (CNS), where there are many diseases for which causative genes have been identified but for which there are no effective treatments.**
  - ・A candidate product for triplet repeat disease*, aiming to enter clinical trials in FY2026.
- **In the long term, we will continue to create distinctive drugs in the DMD and CNS fields by utilizing new drug discovery modalities.**
  - ・Work on Nucleic acid drugs that utilize nucleic acid-loaded exosomes, gene expression-enhancing nucleic acids, RNA editing and RNA trans-splicing, and work on oral nucleic acid drugs, etc.
  - ・Work on the development of "nucleic acid/small molecule complex drug" which combines the features of nucleic acid drug discovery and small molecule drug discovery.

*Triplet repeat disease: a genetic neurological disease caused by abnormal elongation of three-base repeat sequence (triplet repeat) in the gene (Fragile X syndrome, Huntington's disease, Spinal and bulbar muscular atrophy, etc.).

Strengthening Five Management Foundations

①Promoting Sustainability Management for Realizing a Sustainable Society

**To realize a sustainable society, we will engage in activities to resolve our five materialities.
A new department dedicated to investor relations was established to strengthen information disclosure.
With promoting initiatives for environment and social issues, 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 in 2035.**

Environment

- Greenhouse gas reduction target (FY2030)
  - ・Scope 1+2 : -42% (compared to FY2020)
  - ・Scope 3 Category 1 : -25% (compared to FY2020)
- Resource management and resource recycling
  - ・The percentage of recycle waste plastic 65% or more
  - ・Continuous reduction of water consumption per 100 million yen

Society

- ・Reduce human rights risks by implementing due diligence, etc.
- ・Continuous contributions to healthcare through public research grant system

Governance

- ・Strengthening the global governance system
- ・Strengthening risk management framework

Improve recognition by external parties and corporate value through information disclosure

Scope 1: Direct GHG emissions from owned or controlled sources, Scope 2: Indirect emissions from the generation of purchased electricity and heat
Scope 3: Indirect emissions, other than Scope1 and Scope 2 emissions, from the supply chain, Category 1: Purchased products and services

Increase efficiency and speed of drug discovery research

Establish a system to launch one in-house product per year

- **Resource allocation and project prioritization to determine which and how much of the limited resources will be invested in which areas.**
  - ・Achieve a balanced R&D pipeline portfolio by investing based on priorities. (probability of success, profitability, focus areas, business value, etc.)
- **System and initiatives to achieve the launch of one in-house product per year**
  - ・ Establish a new collegial decision-making council to ensure prompt information sharing, issue resolution, and thorough progress management.
  - ・ All researchers propose new themes.
  - ・ Shorten timeframe by organizing and optimizing the drug discovery process.
- **Promote efficient research and development using AI**

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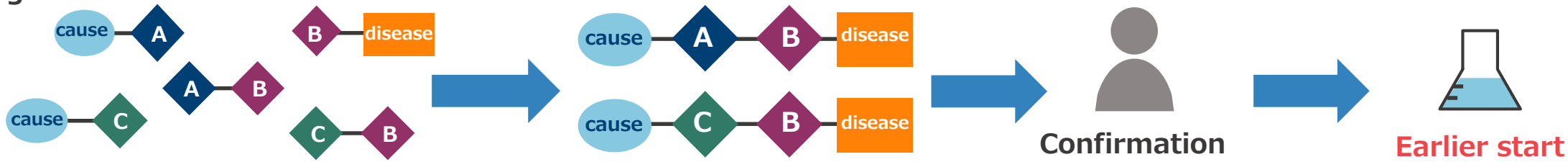


Huge amount of information on diseases, symptoms, genes, etc. in papers and databases

Gathering information and creating inferences using AI

② Speeding Up R&D

Speed up clinical development by flexibly changing the global development system according to the pipeline, strengthening the response to regulatory authorities in each country, accelerating the timing of investment with an eye to the next phase, and creating robust study plans and confirming feasibility.

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 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

Maximizing individual potential without increasing the number of domestic human resources, we will become a small but unique team.

Global

- Acquisition and development of human resources capable of performing on a global scale
- Increase in the number of local human resources with global expansion in the U.S., China, and Europe.

Domestic

- The placing of the right employee in the right position, Selection of younger employees, Implement motivation in management
- Development of human resources who can promote BPR (Business process reengineering) through the use of digital technology.

< Action to achieve the goal >

Human Resources Strategy

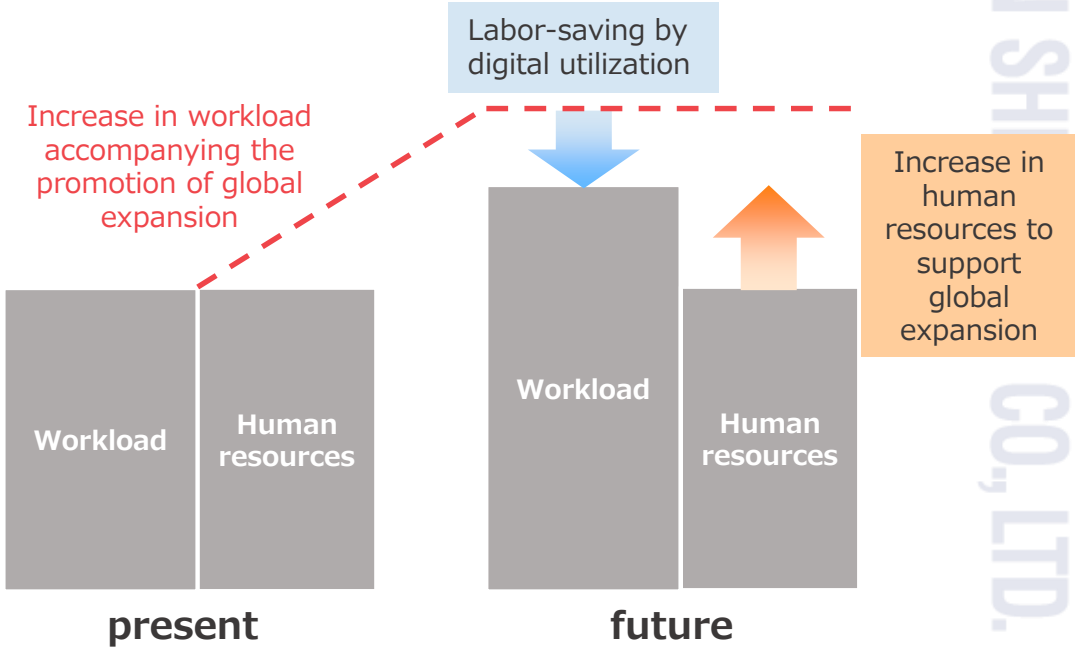
- Acquisition and development of human resources to support global expansion
- Development human resources to promote company-wide DX
- Providing opportunities to experience different cultures
- Realization of treatment that suits there roles, responsibilities, and performance
- Realization of proactive career development and the right people in the right places

×

Organizational Culture Reform

- Penetrating Vision 2035 through Nippon Shinyaku Group
- A small but unique team
- Well-being, engagement
- Creating a highly psychologically safe environment

< Balance between employee and workload >



Since digital technology is advancing rapidly, we will invest in digital systems and human resource development to take advantage of it proactively. We will take data-driven responses quickly to issues from R&D or sales promotion.

It is difficult to make profits continuously without improving operational efficiency and productivity while promoting globalization.

⇒ We will determine "DX themes" that should be prioritized and promote them with the involvement of the management team.

To change the way we do our daily work and increase productivity, we will develop "human resources for BPR" who can actively utilize digital technology as well as make all employees had digital skills and digital literacy.

Development of human resources for DX	KPI
Human resources for BPR	10% of all employees
Human resources for promoting DX	25% of all employees
Fixation ratio of basic knowledge for DX	100% of all employees

Digital for Smiles

—Let's Be Digital to Bring Smiles to People around the World—

Strategy 1
Digital for Innovation
We will provide people around the world with better products and services more quickly.

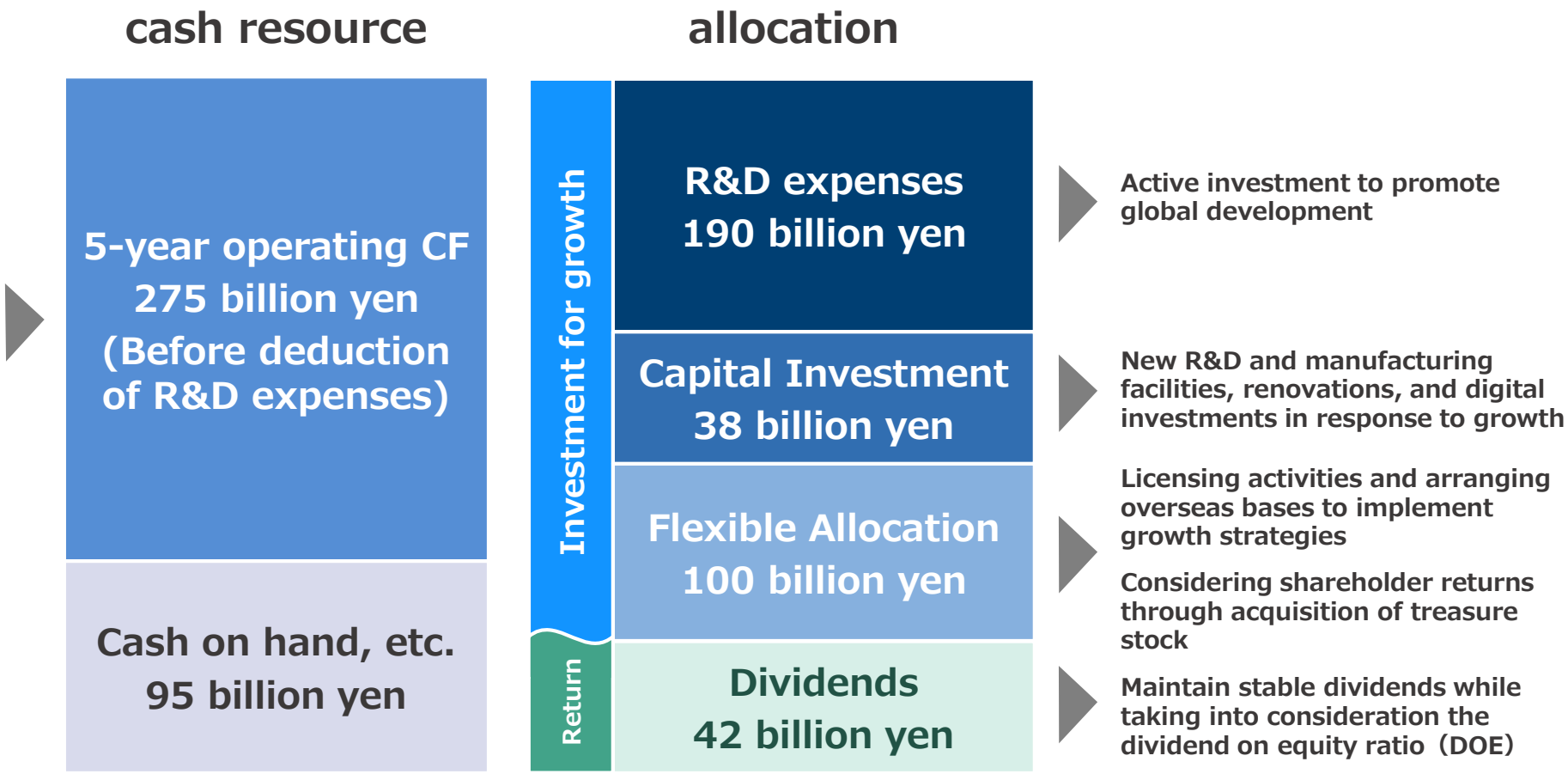
Strategy 2
Digital for Operation
We will strengthen our management foundation and shift streamlined operational resources to creative areas.

Strategy 3
Digital for Adaptation
We will promote the development of organizations and human assets suitable for the digital age.

⑤Financial Strategy for Sustainable Growth

Develop a capital allocation and make strategic investments necessary for sustainable growth while ensuring financial soundness.

Maximize operating CF by promoting the three key themes toward “Vision for 2035”



Management Targets

Targets in FY2028

We will achieve our targets by strategically investing our management resources to strengthen our three key themes and five management foundations.
To lay the foundation for a company with sales of 300 billion yen in FY2030, and beyond that, a company with sales of 500 billion yen.

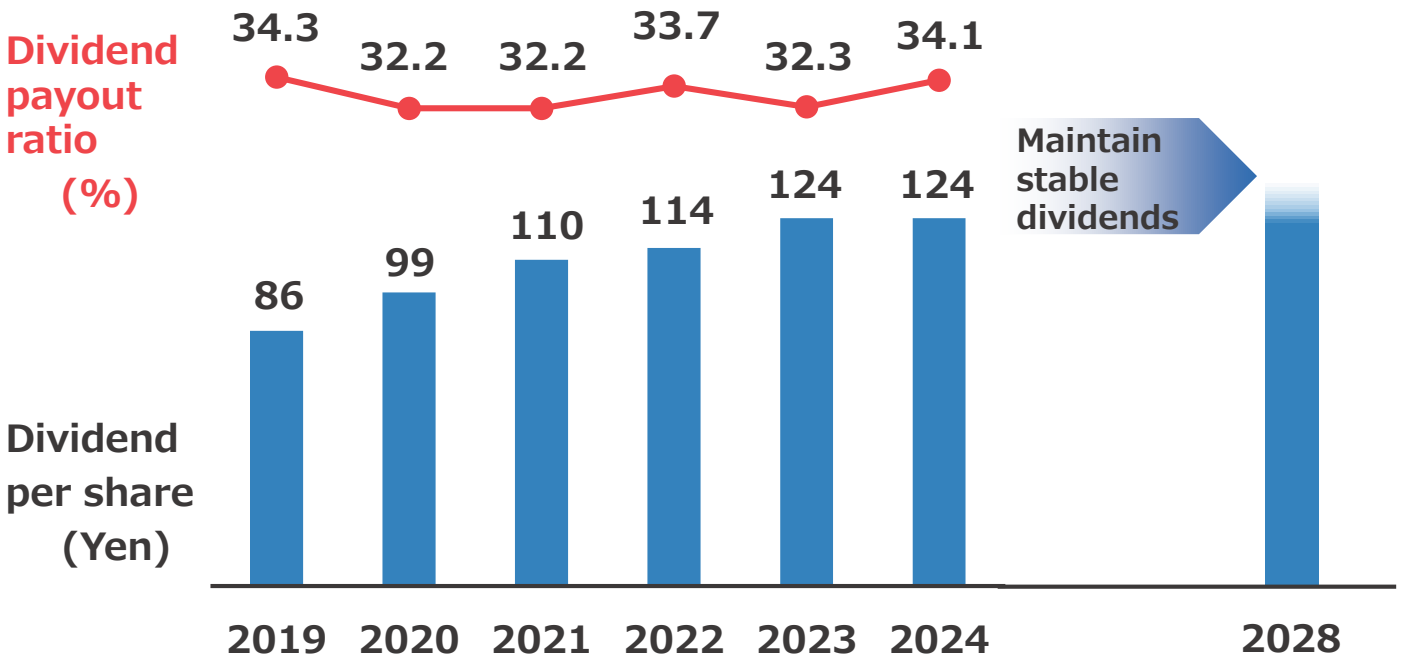
	FY2023	FY2028
Revenue	148.2 billion yen	230 billion yen
Operating profit	33.2 billion yen	30 billion yen
EPS	383 yen	341 yen
ROE	12.4%	≧ 8%
ROIC	19.3%	≧ 9%
1USD	144.6 yen	140.0 yen

Shareholder Returns

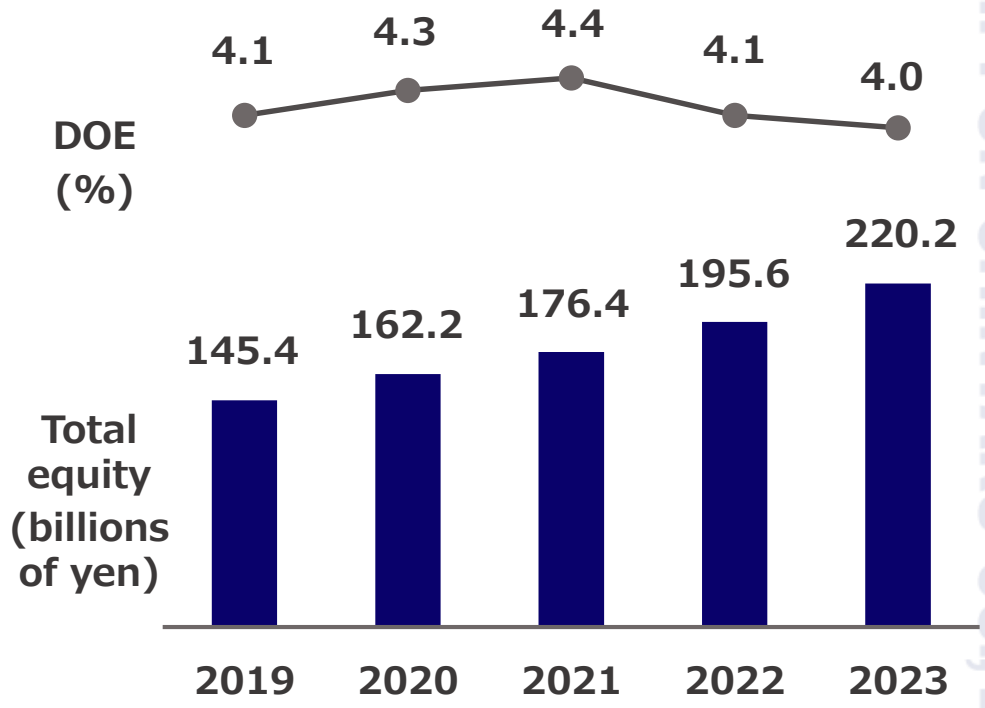
Shareholder Returns Policy

The Company's policy is to maintain stable dividends while taking into consideration the dividend on equity ratio（DOE）.

Dividend Payout Ratio and Dividend per Share



DOE and Shareholders' Equity




Toward a society where good health is
enjoyed by everyone around the world

Safe Harbor Statement

- Materials and information provided during this presentation may contain so-called “forward-looking statements.” These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially from these statements.

- Risks and uncertainties include general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations. Risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, technological advances and patents attained by competitors; challenges inherent in new product development, including completion or failure of clinical trials; claims and concerns about product safety and efficacy; regulatory agency’s examination, obtaining regulatory approvals; domestic and foreign social security reforms; trends toward healthcare cost containment; and governmental laws and regulations affecting domestic and foreign operations.

- Also, for products that are approved, there are manufacturing and marketing risks and uncertainties, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials, and competition with others.

- The Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

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NIPPON SHINYAKU CO., LTD.

NIPPON SHINYAKU CO., LTD.

Nippon Shinyaku Co., Ltd.

7th Five-Year Medium-Term Management Plan Meeting

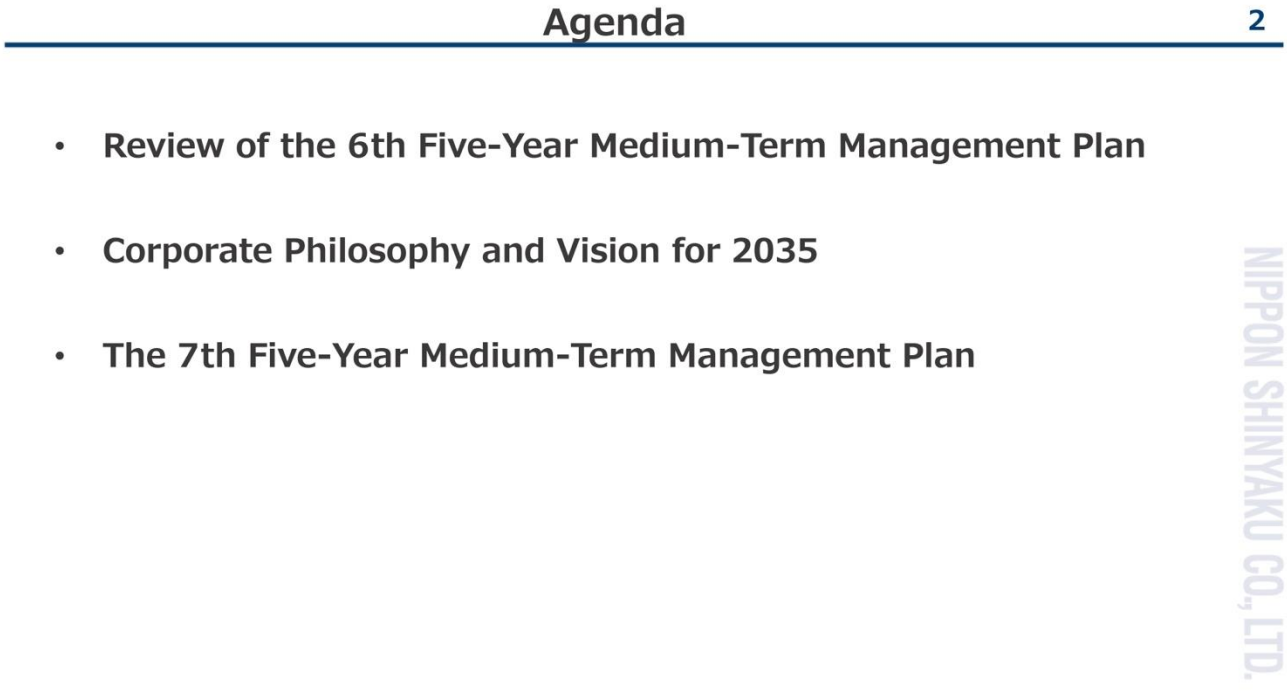
May 28, 2024

Presentation

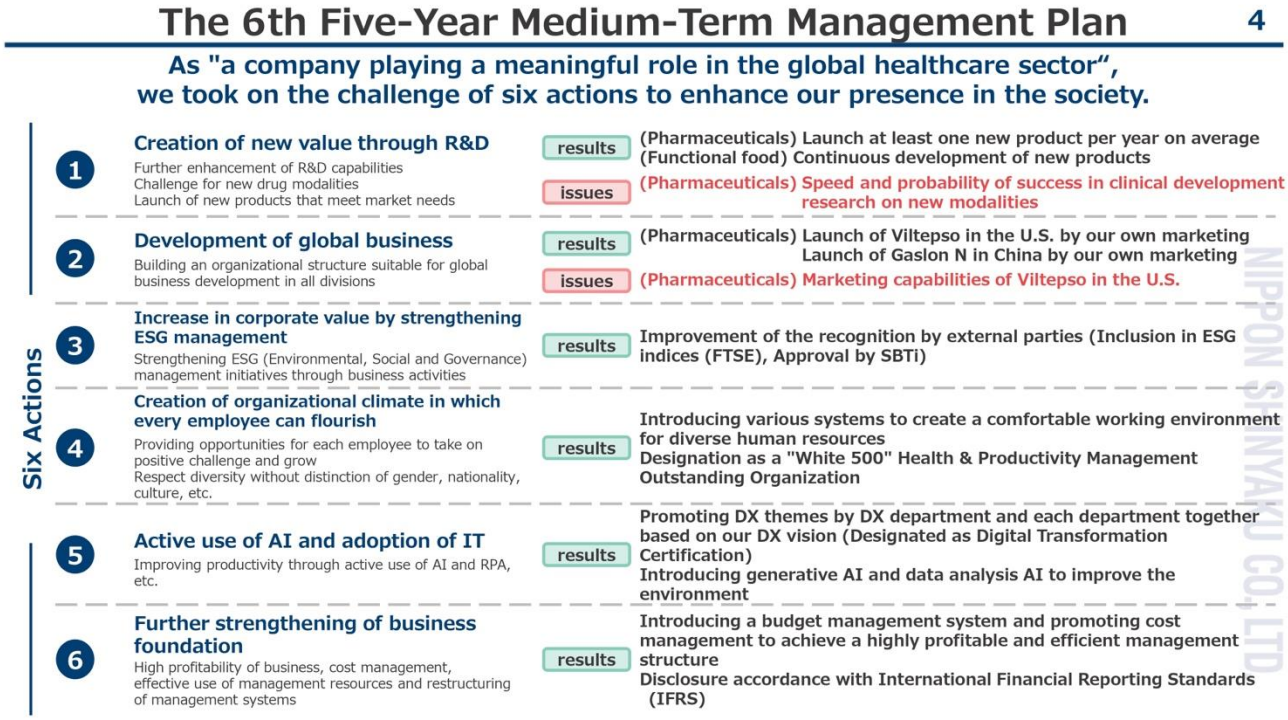
Nakai: I am Toru Nakai, President of Nippon Shinyaku, Co., Ltd.

Thank you very much for taking time out of your busy schedule to participate in our 7th Five-Year Medium-Term Management Plan Meeting. I appreciate it very much.

I will now give an overview of our 7th Five-year Medium-Term Management Plan, "For Global Growth Beyond the Cliff," which began in April of this year.



This is what we will be discussing today.

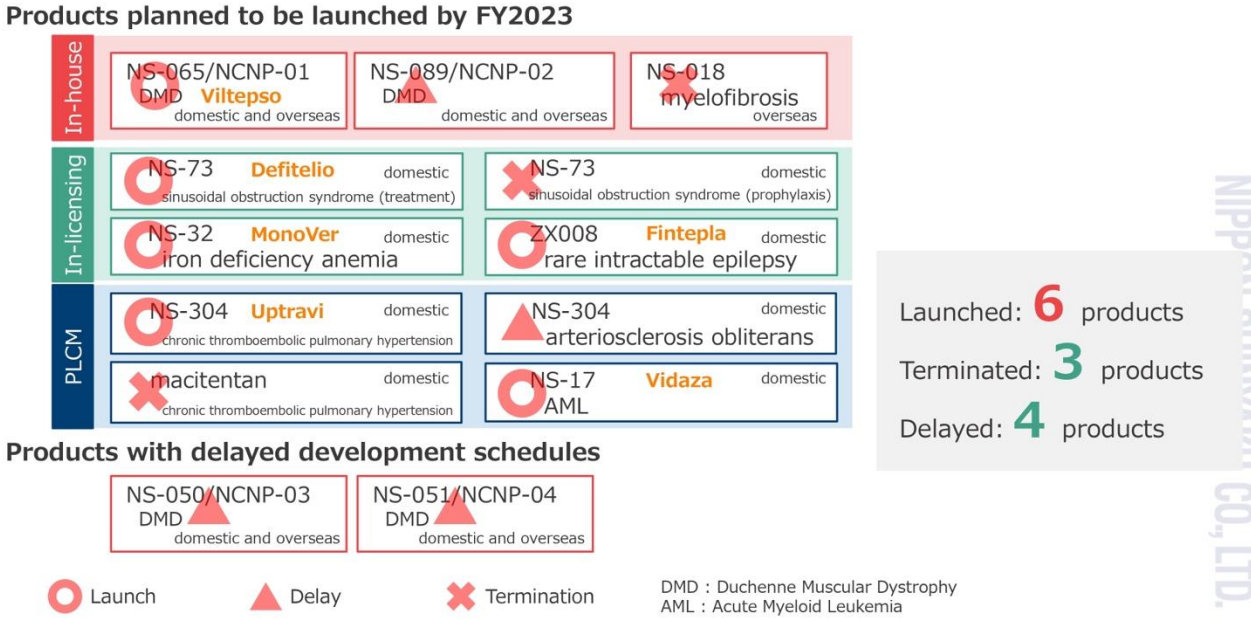


To begin, I would like to review our 6th Five-Year Medium-Term Management Plan, which began in April 2019 and ended in March of this year.

In the 6th Five-Year Medium-Term Management Plan, we have taken on the challenge of the six initiatives shown here with the aim of enhancing our significance in society as "a company playing a meaningful role in the global healthcare sector."

As a result, although there are issues to be overcome, such as the speed of R&D, we were able to achieve results in each of the six initiatives, including the launch of an average of at least one new product per year, the start of in-house sales of Viltepso in the US, SBTi approval, continued recognition as a White 500 company, and acquisition of DX certification.

Products Planned to Be Launched During the 6th Medium-Term Management Plan 5



This slide shows the items planned for launch at the time of disclosure of the 6th Medium-Term Management Plan and the status of achievement for each item.

By launching Viltepso, Defitelio, Monover, and Fintepla, as well as expanding the indications for Uptravi and Vidaza to a total of six new products, we were able to achieve our goal of launching an average of at least one new product per year.

On the other hand, the development of NS-018 was discontinued and the development of three subsequent nucleic acid drugs was delayed.

Major Management Issues

During the 7th Medium-Term Management Plan, we will resolve issues identified in the 6th Medium-Term Management Plan.

We believe that the 6th Medium-Term Management Plan clarified issues such as "speed and probability of success in clinical development, speed of R&D for new modalities, and overseas sales capabilities," and we will work to resolve these management issues in the 7th Medium-Term Management Plan.

Targets of the 6th Medium-Term Management Plan

Among FY2023 targets in the plan, we have achieved functional food segment revenue an company ROE.

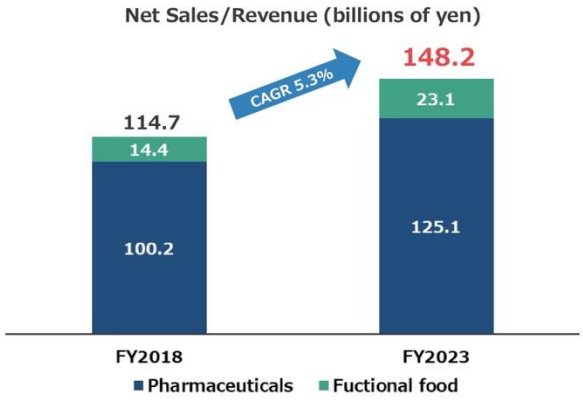
	Target in FY2023	Results in FY2023
Revenue	150 billion yen	148.2 billion yen
Pharmaceuticals	133 billion yen	125.1 billion yen
Functional Food	17 billion yen	23.1 billion yen
Operating profit	40 billion yen	33.2 billion yen
Profit attributable to owners of parent	30 billion yen	25.8 billion yen
EPS	445 yen	383 yen
ROE	10% or more	12.4%

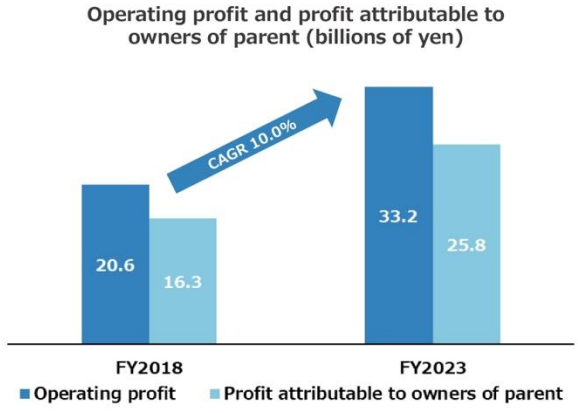
Regarding the quantitative plan, the functional foods segment and ROE achieved their targets. On the other hand, in the pharmaceuticals segment, royalty income from Uptravi exceeded the plan, partly due to the weak yen, but fell short of the plan due to the implementation of the annual revision of NHI drug prices and the failure to achieve the expected start-up of new products due to the effects of the global outbreak of COVID-19, including the suppression of medical treatment and consultations.

In terms of profit, each profit was below target due to aggressive overseas expansion efforts, higher selling costs due to inflation in the U.S., and higher R&D expenses.

Summary of Review of the 6th Medium-Term Management Plan 8

In the 6th Medium-Term Management Plan, we established a foundation for global expansion through working on our own marketing in the U.S. and China, and achieved growth with record high revenue and respective profits.





Although we did not reach the quantitative targets of the medium-term management plan, we believe that we were able to achieve sustainable growth, with record-high sales and respective profits in the final year of the plan, by achieving the establishment of a foundation for global expansion, including our own sales efforts in the US and China.

Environmental Recognition 10

External environment

<Global>
- Population growth
- Advancement of R&D
- Development of AI and digital technology
- Climate change
- Increase in natural disasters
- Increased geopolitical risk
- Diversification of values

<Japan>
- Declining birthrate and aging population
- Population decline
- Promotion of generic products
- Annual NHI price revision
- Drag lag and drug losses

Internal environment

<Nippon Shinyaku>
- Management issues from The 6th Medium-Term Management Plan
- Uptravi's patent cliff
- Increase in R&D expenses

Important initiatives for Nippon Shinyaku

- **In a drastically changing business environment, we see not only Japan but also the global market as a growth market.**
- **We will respond quickly to technological evolution with an enterprising spirit.**
- **We will provide products and services that meet the diversifying needs of people's lives.**

Next, I will explain the corporate philosophy and vision that form the premise of the 7th Medium-Term Management Plan.

We believe that the business environment surrounding our Company will continue to change drastically in the future: on a global scale, with the advancement of R&D, the development of AI/digital technology, and the diversification of values; and in Japan, with the low birthrate, aging and declining population, and the strengthening of measures to control medical costs.

As for the internal environment, management issues became clear during the 6th Medium-Term Management Plan period, and in addition to the increase in R&D expenses, we are preparing for the patent cliff of Uptravi.

In this environment, we believe it is important to view the global market as a growth market, to respond quickly to increasingly sophisticated technologies with an enterprising spirit, and to provide products and services that meet the diversifying needs of people's live.

Therefore, based on this recognition of the environment and our corporate philosophy, we have established a long-term vision of how we want to be by 2035.

In 2035, we would like to become "a global healthcare company from Kyoto creating various types of new ways of life for each person around the world."

In other words, amidst the diversity of ways of thinking and living, we aim to contribute to society by addressing the concept of "to live" in order to fulfill our corporate philosophy of "contributing to the creation of healthy and fulfilling lives for people."

Realization of Management Philosophy and Vision for 2035 12

In two business segments of pharmaceuticals and functional food, we will differentiate ourselves from competitors and achieve continuous new product launches globally. Through these initiatives, we aim to resolve issues of materiality and achieve Vision for 2035 "A global healthcare company from Kyoto creating various types of new ways of life for each person around the world".

There are as many ways of life as people

Pharmaceuticals | Functional food

With thinking lives of all people based on patient centricity and client perspective, we will create a new way of life by products or services based on two business segments, pharmaceuticals and functional food, and contribute to help people lead healthier, happier lives.

In order to contribute to people's "to live," we will continue to work on two businesses: pharmaceuticals and functional foods. Through both businesses, we will deliver a new way of "to live" to the world by providing products and services that differentiate us from our competitors, with an awareness of Patient Centricity and the customer perspective.

Toward the Realization Vision for 2035 13

Toward realizing Vision for 2035, we aim to resolve issues of materiality by integrating management policy and sustainability policy in our operations.

Management Policy

Basic Policies to achieve Vision for 2035

- Supply Unique and High-quality Products and Services (customers)
- Earn the Trust of Society (society)
- Develop Each Employee (employees)

Sustainability Policy

Policies to clarify our stance on promoting sustainability management

Recognizing responses to environment and social issues as material in our management, Nippon Shinyaku Group aims to realize a sustainable society. To fulfill this aim, the Group conducts educational and awareness-raising activities intended for all employees to further develop conscious of sustainability among them.

Materiality

①Realizing a healthy future by creating innovation
②Developing diverse human resources and realizing employee well-being
③Resolving social issues and coaxing with the community
④Strengthening efforts to protect the global environment
⑤Strengthening governance

Vision for 2035

A global healthcare company from Kyoto creating various types of new ways of life for each person around the world

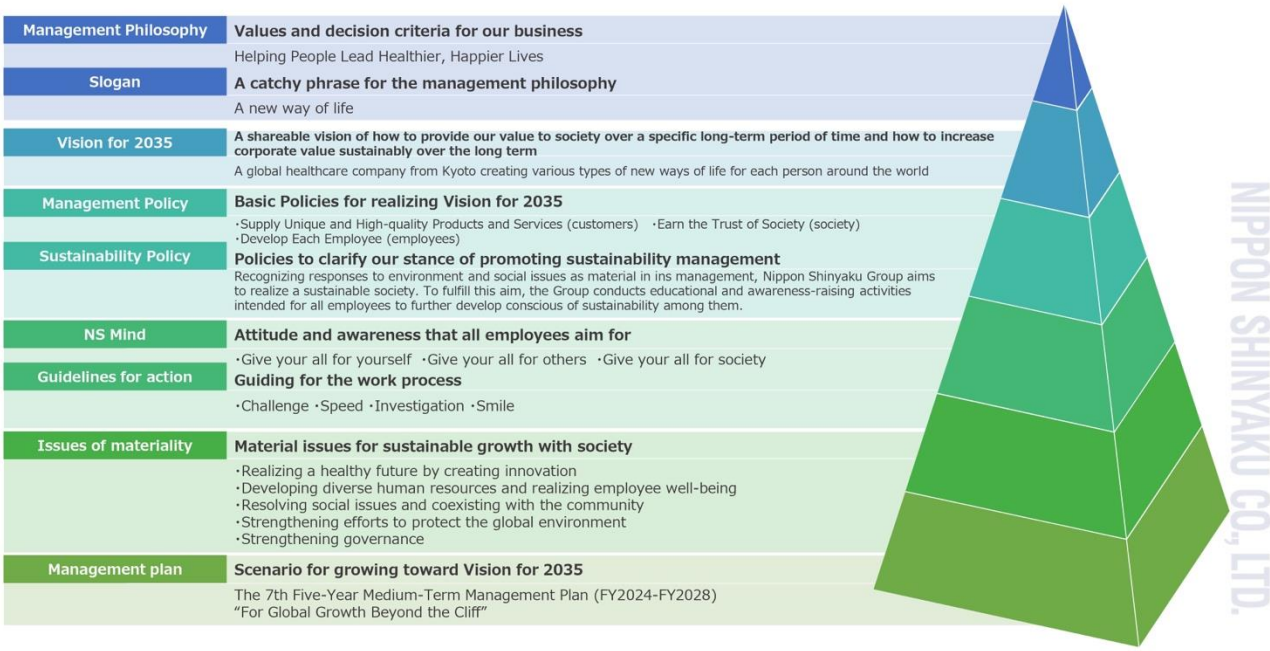
In March 2023, we revised the issues of materiality due to drastic changes in our business environment

Changes in the business environment

- Increase in R&D expenses
- Uptravi's patent cliff
- Declining birthrate and aging population
- Promotion of the generic products
- Development of AI and digital technology
- Advancement of R&D
- Natural disasters
- Annual NHI price revision

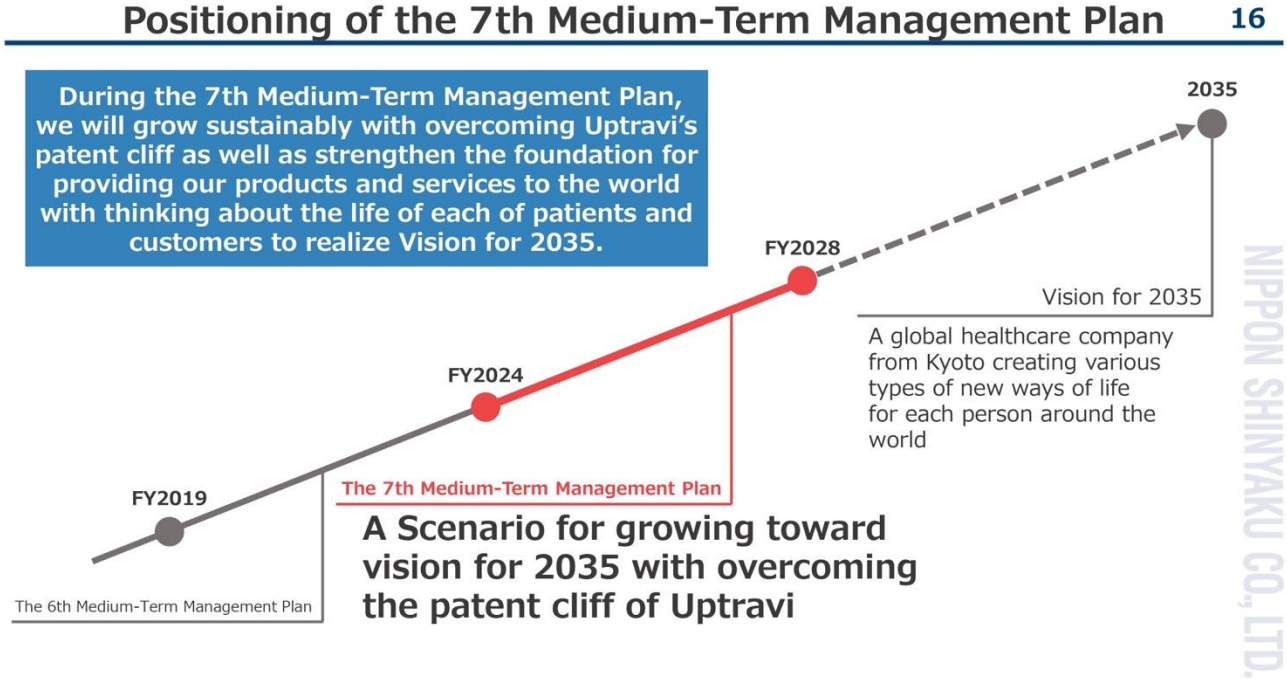
In addition, in consideration of the changing environment and ease of understanding shown here, we revised to simplify the number of materiality issues to five in March 2023. We believe that the ideal state in 2035 is the state that can be achieved through management that sees the management policy and the sustainability policy as one and the same, and through efforts to resolve materiality.

Overview of Management



In summary, we will conduct our business to contribute to the creation of healthy and affluent lifestyles, which is our corporate philosophy, and aim to realize our vision of what we want to be in 2035. To this end, we will manage our business by integrating our management policy and sustainability policy, and all employees will practice the NS Mind and Guidelines for action.

In order to ensure our sustainable existence and growth, we have identified materiality, and the 7th Medium-Term Management Plan is designed as a scenario that will also help us resolve materiality.



I will now begin to explain our 7th Five-Year Medium-Term Management Plan, "For Global Growth Beyond the Cliff."

The 7th Medium-Term Management Plan is positioned as a scenario for overcoming the patent cliff and achieving future growth, as well as a scenario for further solidifying the foundation for providing products and services to the world by considering "to live" of each and every patient and customer, with the aim of realizing our ideal state by 2035.

Establishing a Foundation for Growth Overcoming the Patent Cliff 17

The patent of Uptravi, which has supported Nippon Shinyaku's growth, will expire in FY2027, and royalty revenue, which accounts for the majority of revenues from the licensing of industrial property rights, are expected to decline significantly.
During the 7th Medium-Term Management Plan, we will focus on overcoming Uptravi's patent cliff by prior investment for future growth and establishing a revenue base that is not dependent on royalty revenue.

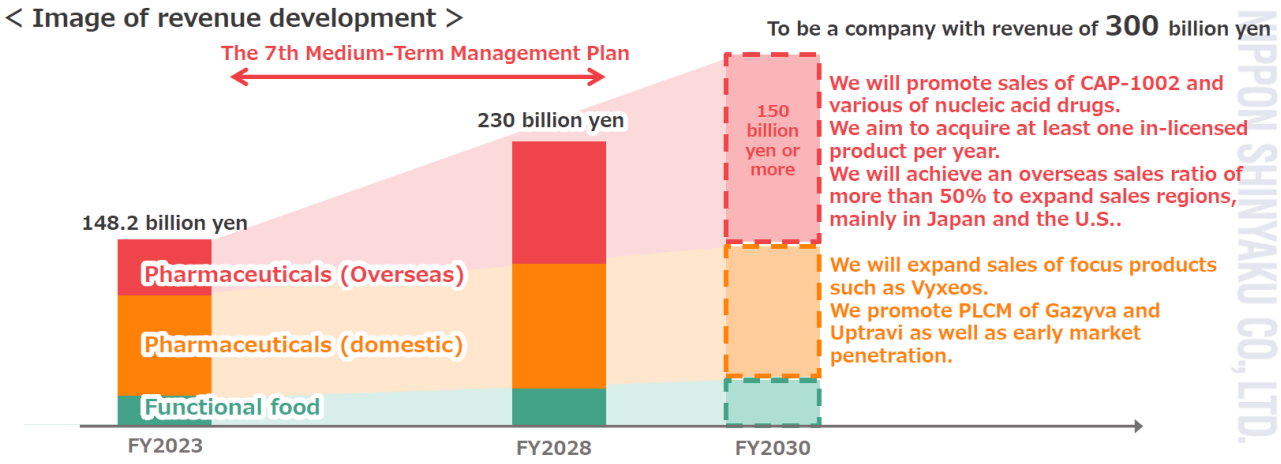
<Image of operating profit development>

Although we have achieved significant growth with Uptravi, we expect a significant decrease in royalty income in FY2028, the final year of our medium-term plan, due to its patent expiration.

During the 7th Medium-Term Management Plan period, profits are expected to temporarily decline due to prior investments for future growth, but we will focus on overcoming patent cliffs and establishing a revenue base that is not dependent on royalty income, aiming for an operating profit JPY50 billion scale in FY2030.

Establishing a foundation for growth overcoming the patent cliff 18

We plan to achieve revenues of 300 billion yen in FY2030 by promoting investment in R&D pipeline, in-licensed products, M&A, etc. during the 7th Medium-Term Management Plan period.



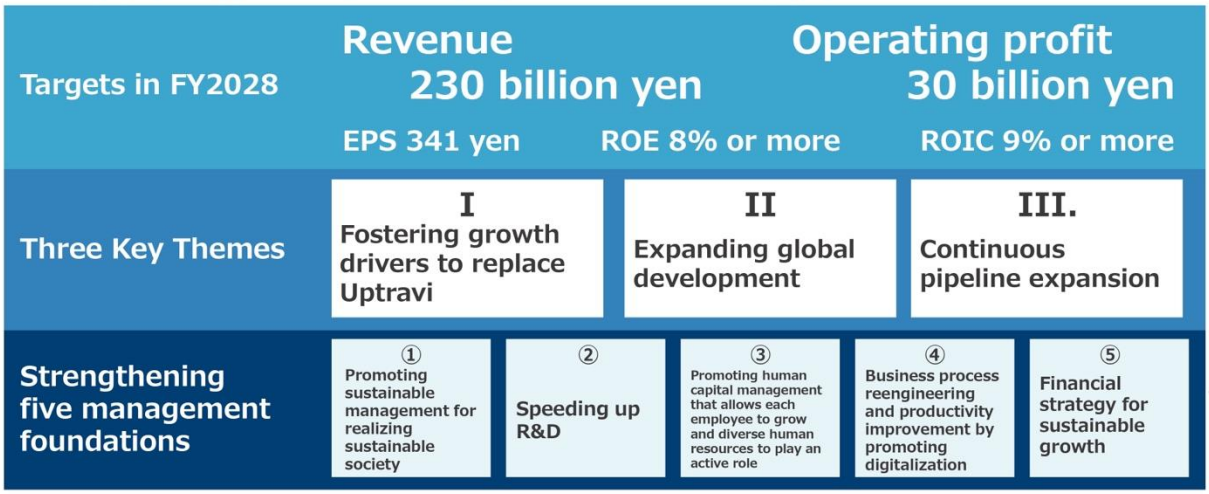
During the 7th Medium-Term Management Plan period, we will invest in R&D, acquisition of in-licensed products, M&A, etc., promote sales of CAP-1002 and nucleic acid drug groups, and grow overseas sales more than domestic sales to become a company with sales revenue of JPY300 billion and overseas sales ratio of over 50% in FY2030.

In other words, as I indicated as my commitment when I became the president, I have drawn up a scenario in which we will achieve our goal of more than doubling our FY2020 actual sales and operating income.

Overview of the 7th Medium-Term Management Plan

During the 7th Medium-Term Management Plan, we will promote "three key themes and strengthening five management foundations" to realize Vision for 2035. In each of the Pharmaceuticals and Functional Food segments, we will thoroughly allocate management resources and reduce costs by prioritizing them based on business strategies, and manage the capital efficiency of each segments by ROIC* to secure earnings that exceed the cost of capital.

*ROIC (%) = Operating profit after tax / Invested capital (Non-current assets + Net working capital)



As part of the process of achieving the targets for FY2030, we target sales revenue of JPY230 billion, operating profit of JPY30 billion, EPS of JPY341, ROE of 8% or higher, and ROIC of 9% or higher for FY2028, the final year of the medium-term management plan.

To this end, the 7th Medium-Term Management Plan promotes three key themes and the strengthening of five management foundations, and aims to achieve this goal by using ROIC as an indicator for management with an awareness of capital efficiency that exceeds the cost of capital in both the pharmaceuticals and functional food businesses.

Business Strategy for Pharmaceutical Segment

Business Strategy

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**: Focusing 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**: Focused as much as in-house drug discovery
- **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 in each region and increase market share

Pharmaceutical Business Segment Targets

	FY2028
Revenue	203 billion yen
Operating profit	28.2 billion yen
ROIC	≧ 9%

I will now outline our business strategies for each of the pharmaceuticals and functional foods segments.

In the pharmaceuticals segment, we will launch an average of two or more new products per year through the three pillars of in-house drug discovery, in-licensing, and PLCM, and will develop the business with priority given to responding to patent cliffs.

In the pharmaceuticals segment, we target revenue of JPY203 billion, operating profit of JPY28.2 billion, and ROIC of 9% or higher in FY2028.

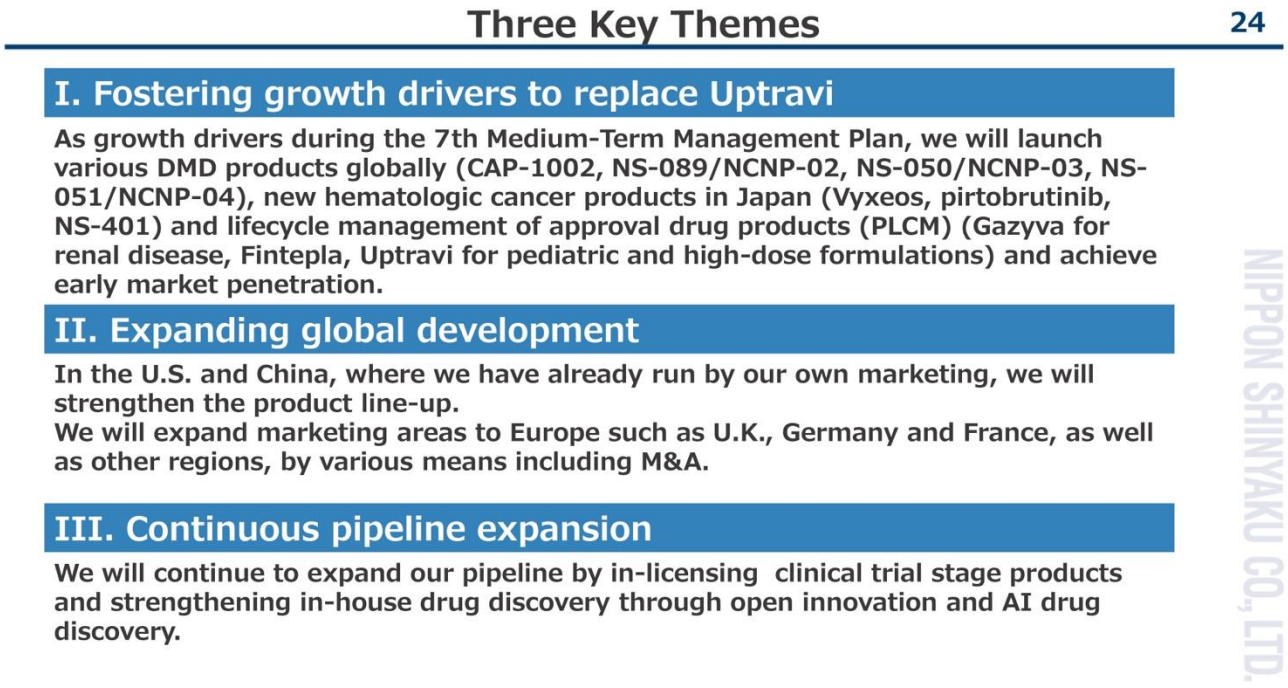
Business Strategy for Functional Food Segment

Business Strategy	Transition to a stable highly profitable structure by providing high quality, unique and high value-added materials and final products.
■B to B Business	Focus on preservatives, for which demand is expected to increase due to the focus on reducing food loss
■B to C Business	Further accelerate growth of sports supplement「WINZONE Whey Protein」 Enhance lineup of anti-aging care supplements by developing new products
■Overseas Expansion	Developing initiatives and systems for business development in Asian countries and other overseas markets

Functional Food Business Segment Targets

	FY2028
Revenue	27 billion yen
Operating profit	1.8 billion yen
ROIC	≧ 9%

In the functional food segment, we will focus on BtoC sports supplements and BtoB quality stabilizing preservatives, and aim to transform the business into a stable and highly profitable structure by providing high-quality, unique, and high-value-added ingredients and finished products, targeting net sales of JPY27 billion, operating profit of JPY1.8 billion, and ROIC of 9% or higher in FY2028.



The following section describes the three key themes of the Seventh Medium-Term Management Plan that will be addressed in overcoming the patent cliff and moving toward subsequent growth.

The "Three Key Themes" are to nurture growth drivers to replace Uptravi, which include the steady launch and early market penetration of products in the DMD drug group, the new blood cancer product group, and the PLCM product group.

In the expansion of global development, we will strengthen our product lineup in the US and China, and expand our sales area to Europe and other regions, including the UK, Germany, and France.

In the ongoing expansion of the pipeline, we will acquire in-licensed products after the clinical stage and strengthen in-house drug discovery through the use of open innovation and AI drug discovery to promote the expansion of the pipeline.

Key Theme I : Fostering Growth Drivers to Replace Uptravi 25

As growth drivers during the 7th Medium-Term Management Plan, we will launch new products in the DMD group, the hematology group, and the PLCM group.

DMD

CAP-1002 : P3 in progress

NS-089/ NCNP-02 : P2 in progress

NS-050/ NCNP-03 : P1 in preparation

NS-051/ NCNP-04 : P1 in preparation

Hematology

Vyxeos : Launch
High-risk acute myeloid leukemia

LY3527727
Mantle cell lymphoma : Application
Chronic lymphocytic leukemia : P3 in progress

NS-401 : P1/2 in progress
Blastic plasmacytoid dendritic cell neoplasm

PLCM

Uptravi : Under application
Pediatric pulmonary arterial hypertension

Fintepla : P3 in progress
CDKL5 gene deficiency

Gazyva : P3 in progress
Lupus nephritis
Pediatric nephrotic syndrome
SLE without nephropathy

As growth drivers during the 7th Medium-Term Management Plan, we will launch four new products for DMD, three new products for hematologic cancers, and new products with expanded indications for Uptravi, Fintepla, and Gazyva.

Key Theme I : Fostering Growth Drivers to Replace Uptravi 26

Within the period of this plan, we plan to launch an average of at least two new products per year.
We aim to acquire at least one in-licensed product each year.
We will conduct an additional P3 study of Viltepso and aim to launch it in Europe and China.

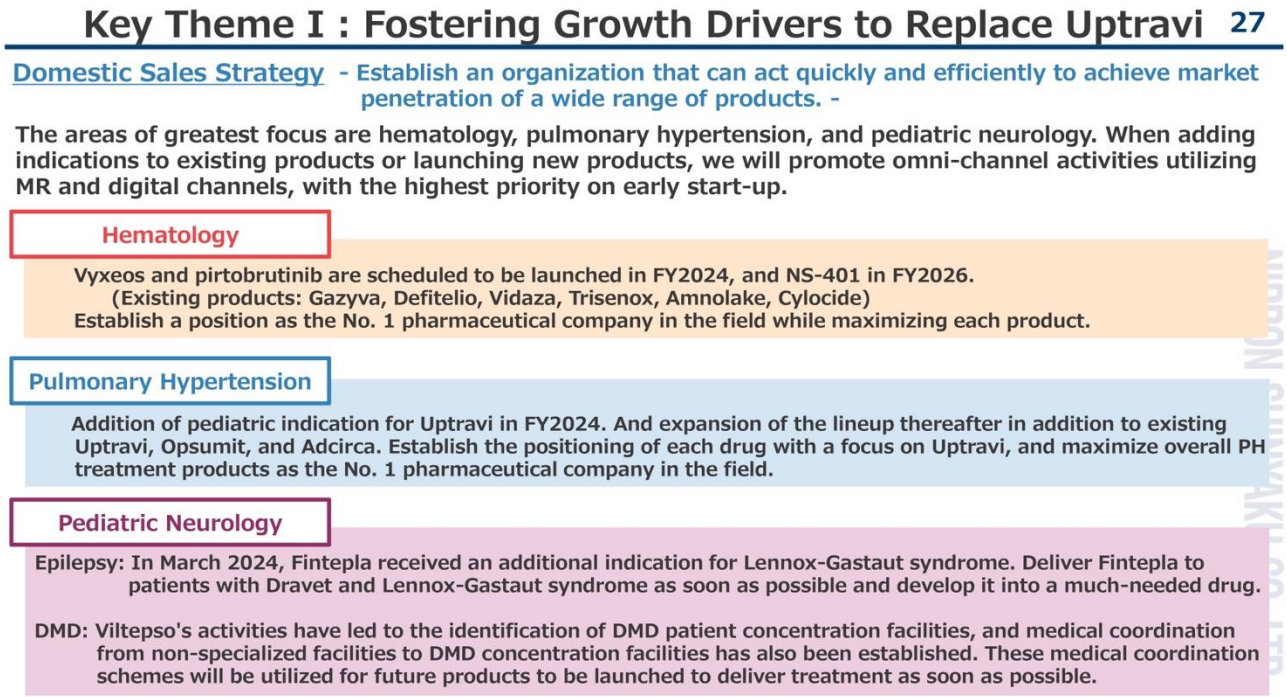
Target for launching new products

	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028
Domestic	NS-87 (VYXEOS) : high-risk AML※		NS-401 : BPDCN※	NS-089/NCNP-02 : DMD	NS-050/NCNP-03 : DMD
	LY3527727 (pirtobrutinib) : 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

※ high-risk AML: high-risk acute myeloid leukemia; MCL: mantle cell lymphoma; pediatric PAH: pediatric pulmonary arterial hypertension; BPDCN: blastic plasmacytoid dendritic cell tumor
The launch date for pirtobrutinib (LY3527727) for chronic lymphocytic leukemia has not been determined.

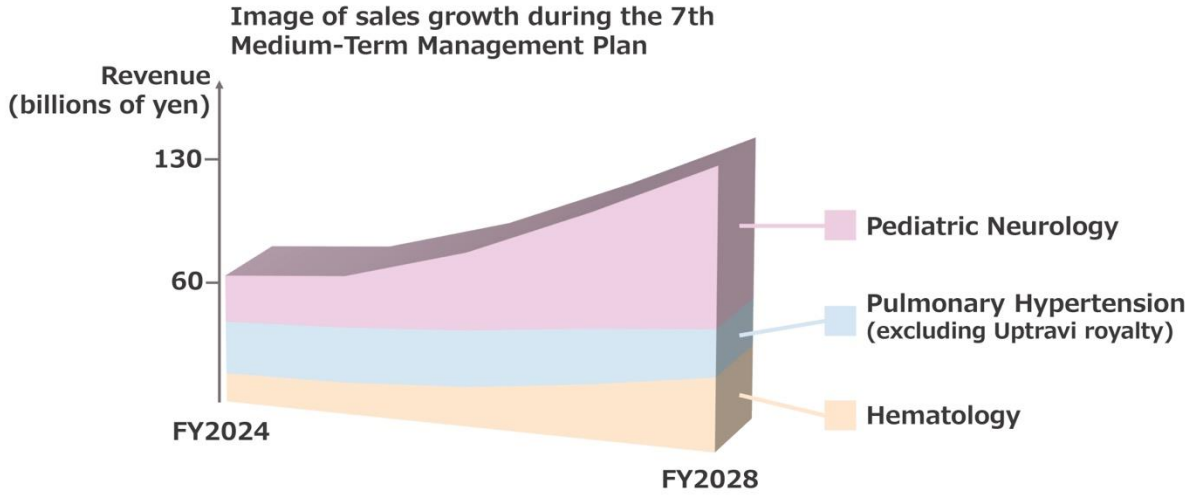
Our detailed launch target, including schedule, is to launch an average of at least two new products per year during the period, depending on new products already in clinical trials, in-licensed products, and PLCM. In addition, we will focus on acquiring new in-licensed products to further expand the number of items on the market.

We will conduct an additional P3 study of Viltepso and aim for approval and launch in Europe and China during the mid-term plan period.



Next, regarding our domestic sales strategy, we will focus on the hematology, pulmonary hypertension, and pediatric neurology fields, aiming to launch products as early as possible in line with PLCM and new product launches. As the way physicians work is changing, we will promote omni-channel activities utilizing the sales rep channel and digital channels to penetrate the market for our products so that they can be used by as many patients as possible.

Global revenue of three focus areas in FY2028⇒ Aiming for over 130 billion yen



In the hematology area, we will promote Vyxeos, as well as pirtobrutinib and NS-401 in Japan, and in pulmonary hypertension, we will further maximize the value of Uptravi by adding pediatric indications. In the area of pediatric neurology, in addition to expanding the indications for Fintepla, we aim to achieve total sales of JPY130 billion or more in 2028 in the three focused areas by globally marketing nucleic acid drugs following CAP-1002 and Viltepso.

Growth Strategies for Overseas Subsidiaries

U.S. subsidiary (NS Pharma, Inc.)

In addition to Viltepso, other DMD investigational drugs (CAP-1002, NS-089/NCNP-02, NS-050/NCNP-03, NS-051/NCNP-04) to be launched

- Increase sales quickly, marketing efficiently
- Expand sales structure (HUB service, Patient support, market access)
- Expand advocacy activities ⇒ Create an environment where patients and their families can continue treatment with peace of mind
- Expand medical activities ⇒ Penetrate a novel cell therapy

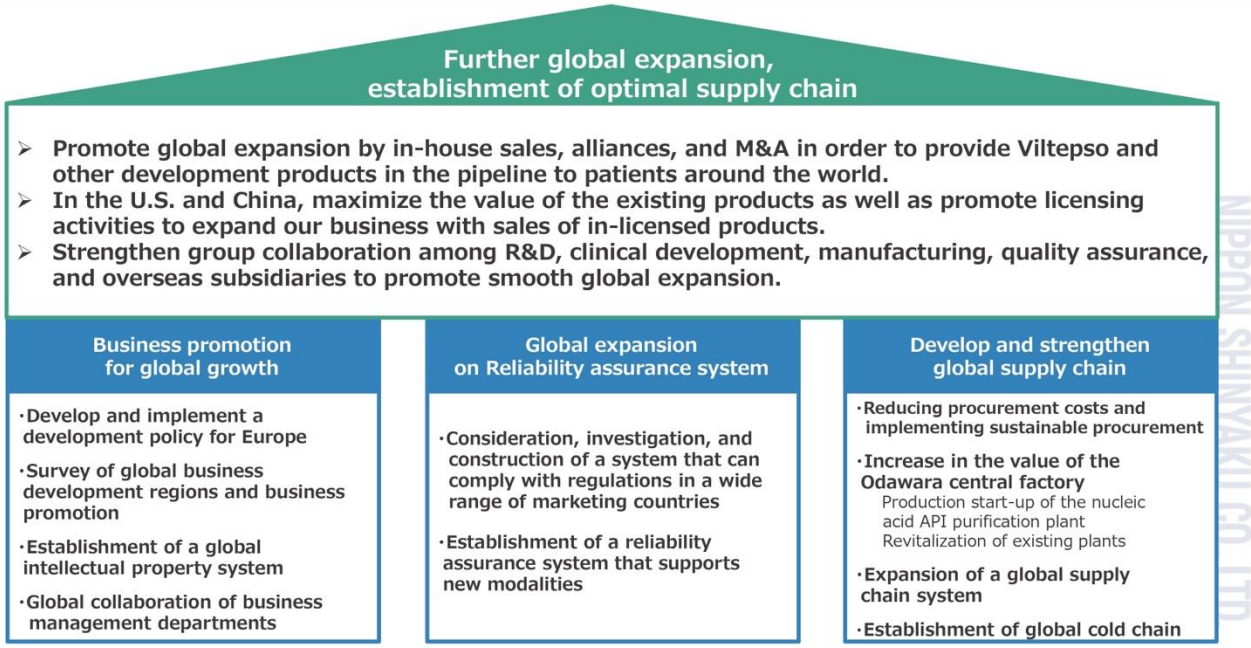
China subsidiaries (Beijing Nippon Shinyaku Co., Ltd.; Tianjin Nippon Shinyaku Co., Ltd.)

Development and establishment of a marketing system for Viltepso and functional food in China

With regard to the second priority theme, expansion of global business development, our US subsidiary NS Pharma plans to launch new DMD treatments such as CAP-1002 in addition to Viltepso. We will focus on effective and efficient marketing and patient-support services with the aim of launching these items as soon as possible.

In addition to preparing for the launch of Viltepso, the Chinese subsidiary will also work to build a sales structure for functional food products in China.

Key Theme II : Expanding Global Development



In addition to strengthening our sales structure in the US and China, we will accelerate our global expansion into Europe and other regions by considering means such as in-house sales, alliances, and M&A in order to provide Viltepso and other items in our pipeline to patients worldwide.

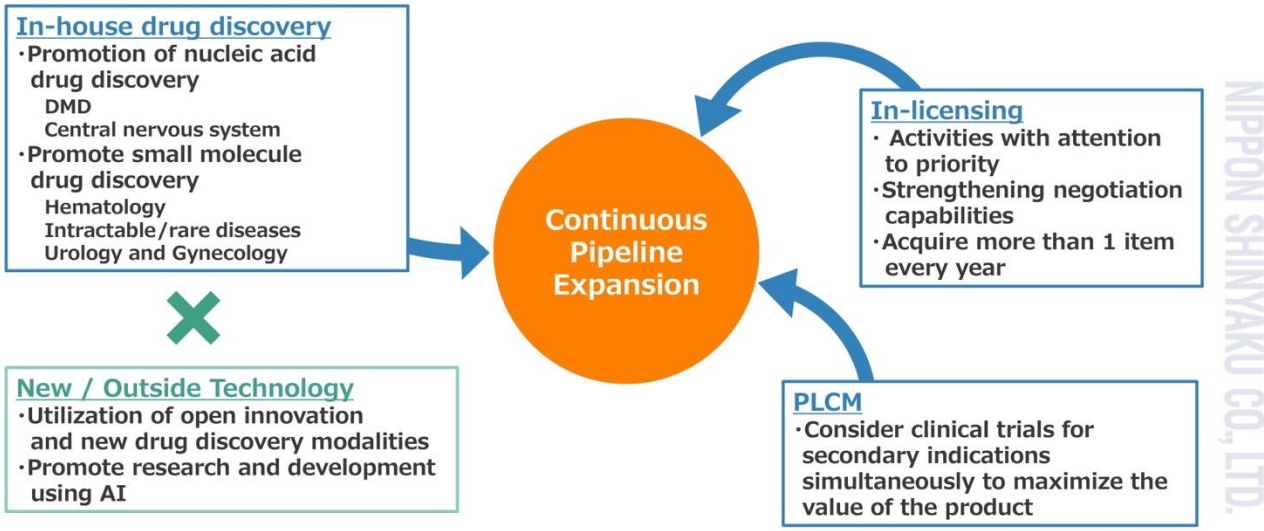
To this end, we will promote our business with an awareness of global growth, and strengthen our reliability assurance system and supply chain globally.

In regions where we have established a sales structure, we will also promote licensing activities with a view to selling in-licensed products.

Through these activities, we will establish a structure that will enable us to supply and market multiple pharmaceutical products globally.

Key Theme III : Continuous Pipeline Expansion

Licensing in products in the clinical stage and strengthen in-house drug discovery by leveraging open innovation and AI drug discovery system to continuously expand the pipeline.



The third key theme is to continuously expand the pipeline based on the three pillars of in-house drug discovery, in-licensing, and PLCM.

For in-house drug discovery, we will work to strengthen the combination of our strengths and other companies' technologies by utilizing open innovation and AI drug discovery.

For in-licensing, priority will be given to items that will lead to global sales, and efforts will be made to acquire at least one in-licensed item per year.

For PLCM, we will begin working on the second indication earlier than before to maximize the value of the drug.

Promotion of Nucleic Acid Drug Discovery

Nucleic acid drugs act on genetic information

↓

・Able to act on previously unapproachable targets
・Enables treatment of the root cause

- **Work on development of nucleic acid drugs for disease of the central nervous system (CNS), where there are many diseases for which causative genes have been identified but for which there are no effective treatments.**
  - ・A candidate product for triplet repeat disease*, aiming to enter clinical trials in FY2026.
- **In the long term, we will continue to create distinctive drugs in the DMD and CNS fields by utilizing new drug discovery modalities.**
  - ・Work on Nucleic acid drugs that utilize nucleic acid-loaded exosomes, gene expression-enhancing nucleic acids, RNA editing and RNA trans-splicing, and work on oral nucleic acid drugs, etc.
  - ・Work on the development of "nucleic acid/small molecule complex drug" which combines the features of nucleic acid drug discovery and small molecule drug discovery.

*Triplet repeat disease: a genetic neurological disease caused by abnormal elongation of three-base repeat sequence (triplet repeat) in the gene (Fragile X syndrome, Huntington's disease, Spinal and bulbar muscular atrophy, etc.).

As for the future development policy for nucleic acid drugs, they are characterized by the fact that they act on genetic information and can act on targets that are difficult to approach with small molecules or antibodies, thus making it possible to treat the underlying cause.

We have been engaged in the discovery of nucleic acid drugs mainly for Duchenne muscular dystrophy, but we will also work on the discovery of drugs for the central nervous system, aiming to enter clinical trials in FY2026.

In nucleic acid drug discovery, we believe that the utilization of new drug discovery modalities, especially through open innovation, will become important, and we will promote initiatives to broaden the scope of drug discovery, such as our joint research with MiNA Therapeutics of the UK.

The next section describes the strengthening of the five management foundations.

To begin with, we can only survive if we have a sustainable society. We promote sustainability management to realize a sustainable society and engage in ESG activities to resolve the five materialities. With regard to IR, we will enhance our corporate value by disclosing information more proactively than ever before, mainly through the dedicated IR department newly established in April of this year to strengthen information disclosure.

Increase efficiency and speed of drug discovery research

Establish a system to launch one in-house product per year

- **Resource allocation and project prioritization to determine which and how much of the limited resources will be invested in which areas.**
  - ・Achieve a balanced R&D pipeline portfolio by investing based on priorities. (probability of success, profitability, focus areas, business value, etc.)
- **System and initiatives to achieve the launch of one in-house product per year**
  - ・Establish a new collegial decision-making council to ensure prompt information sharing, issue resolution, and thorough progress management.
  - ・All researchers propose new themes.
  - ・Shorten timeframe by organizing and optimizing the drug discovery process.
- **Promote efficient research and development using AI**

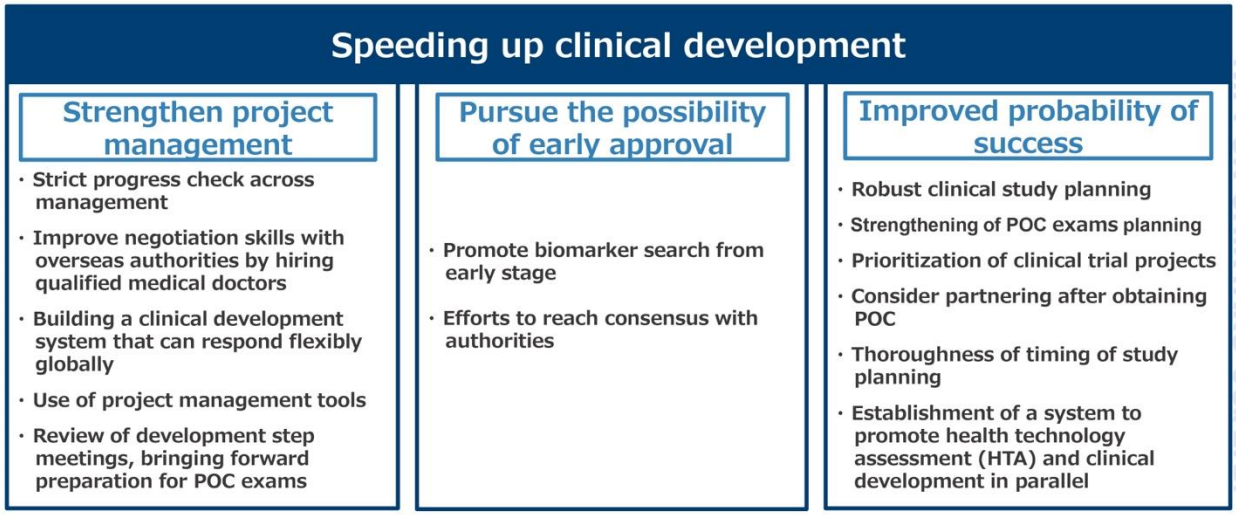
<Image>

The second way to strengthen the management foundation is to speed up research and development. First, 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 will enable us to launch one in-house product per year.

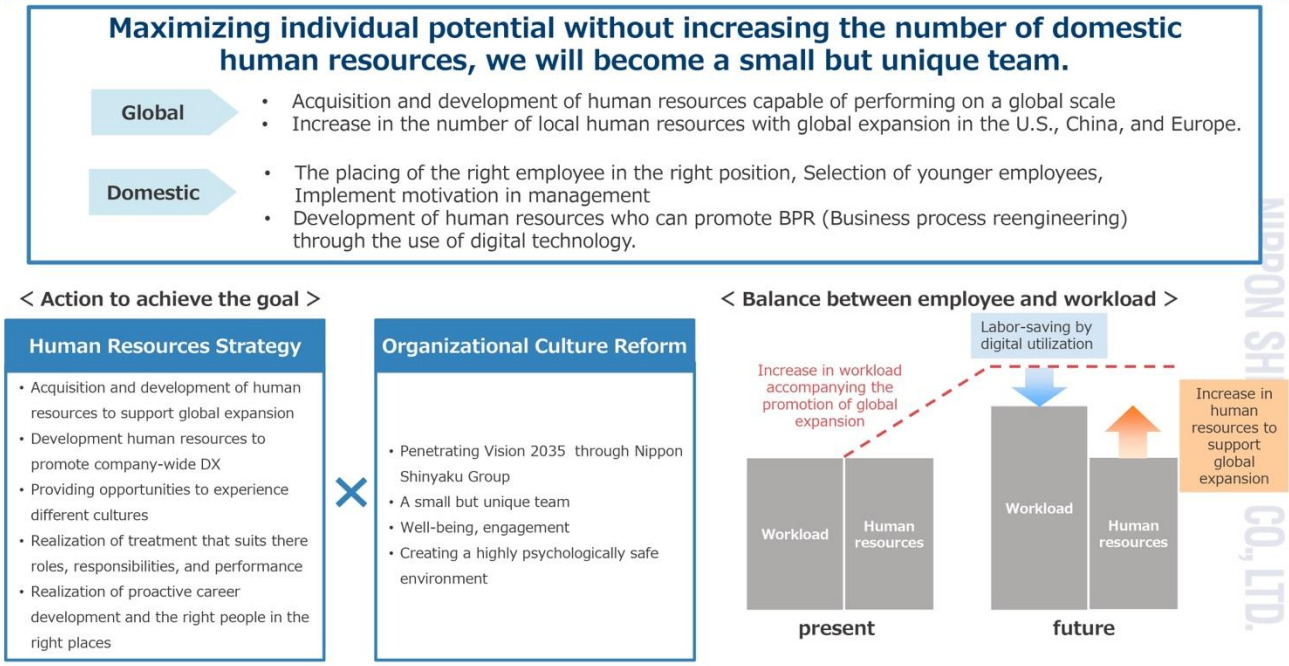
The project will promote prioritization of projects, allocation of management resources, review of decision-making meetings, use of AI, etc. Regarding the use of AI, we will work to have AI collect a vast amount of information on diseases and symptoms in articles and databases, and use it to create inferences that link causes and diseases. By reducing the time it used to take researchers to conduct research and prepare inferences, we will work to speed up the drug discovery research cycle and build a system that will enable us to launch one in-house product per year by starting research activities at an early stage.

② Speeding Up R&D

Speed up clinical development by flexibly changing the global development system according to the pipeline, strengthening the response to regulatory authorities in each country, accelerating the timing of investment with an eye to the next phase, and creating robust study plans and confirming feasibility.



To speed up clinical development, several clinical trials were delayed during the 6th Medium-Term Management Plan period. To resolve these issues, we will focus on strict progress checks by the entire management, strengthening project management by enhancing our response to regulatory authorities in each country and accelerating the timing of investment, pursuing the possibility of expedited approval, developing robust trial speed up the process by focusing on improving the probability of success through planning and conducting feasibility checks.



The third is the promotion of human capital management. In order to promote global development and expand our pipeline, it is necessary for each and every employee to grow and for diverse human resources to play an active role.

While the volume of work will increase as we expand globally, we will maximize the potential of each individual and reform our human resource strategy and organizational culture by acquiring and training human resources who can be active globally, and by saving labor through digitalization, we will respond without increasing the number of domestic employees.

Since digital technology is advancing rapidly, we will invest in digital systems and human resource development to take advantage of it proactively. We will take data-driven responses quickly to issues from R&D or sales promotion.

It is difficult to make profits continuously without improving operational efficiency and productivity while promoting globalization.
⇒ We will determine "DX themes" that should be prioritized and promote them with the involvement of the management team.

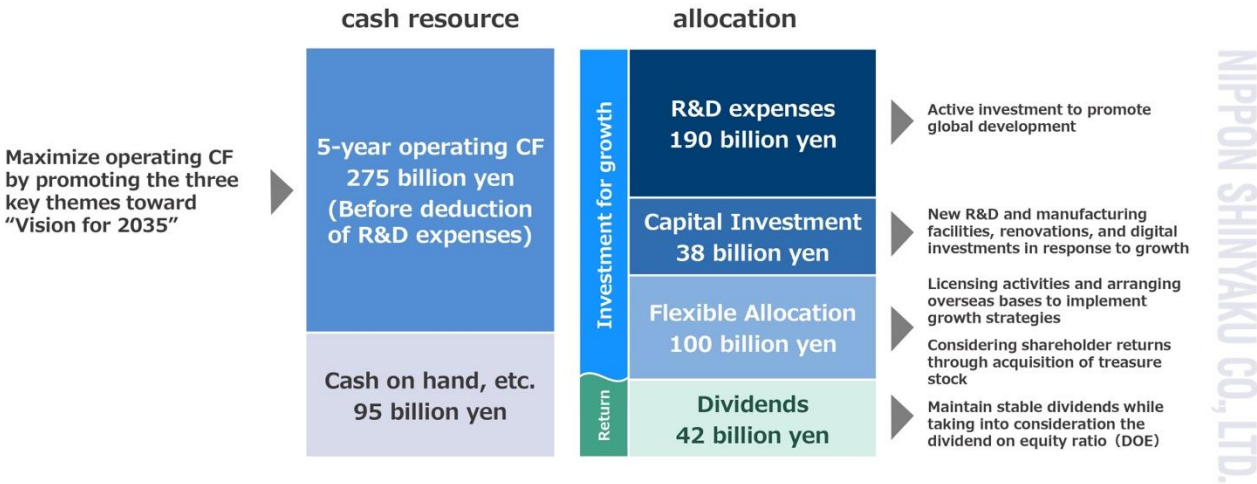
To change the way we do our daily work and increase productivity, we will develop "human resources for BPR" who can actively utilize digital technology as well as make all employees had digital skills and digital literacy.

Development of human resources for DX	KPI
Human resources for BPR	10% of all employees
Human resources for promoting DX	25% of all employees
Fixation ratio of basic knowledge for DX	100% of all employees

To strengthen the fourth management foundation, "business process reengineering and productivity improvement by promoting digitalization," we will also aggressively invest in systems and human resource development. We will respond to issues that arise in R&D and sales promotion activities based on data to speed up and improve efficiency.

We will promote the development of DX human resources by defining transformational human resources as those who are able to identify issues by utilizing business skills in addition to digital technology, and who are capable of making fundamental changes in operations and creating new businesses. In addition, we will promote DX themes internally, with management involvement, to drive company-wide transformation.

Develop a capital allocation and make strategic investments necessary for sustainable growth while ensuring financial soundness.



The fifth is a financial strategy for sustainable growth. The basic policy of capital allocation is to actively make the investments necessary for sustainable growth while ensuring financial soundness.

We are considering a total of JPY190 billion for R&D investment over five years, JPY38 billion for capital investment, including the construction of a new research building at the Drug Discovery Research Institute to respond to new technologies and create innovation, and up to JPY100 billion for flexible allocation, including growth investments such as M&A, in-licensing, and share buybacks, and JPY42 billion in total for shareholder returns. We will ensure financial soundness through a divestiture of the cross-shareholdings and, if necessary, borrowing.

Targets in FY2028

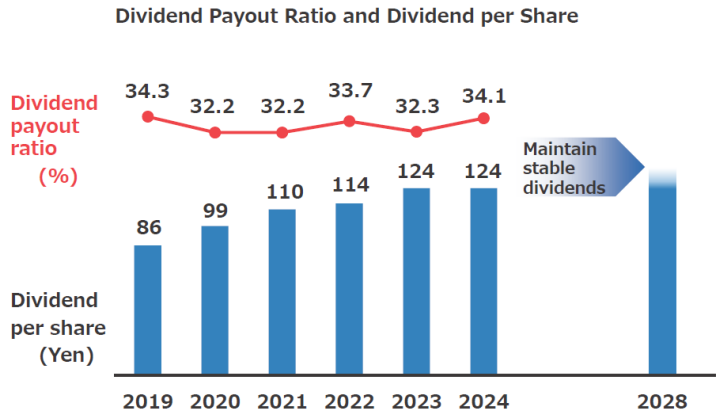
We will achieve our targets by strategically investing our management resources to strengthen our three key themes and five management foundations.
To lay the foundation for a company with sales of 300 billion yen in FY2030, and beyond that, a company with sales of 500 billion yen.

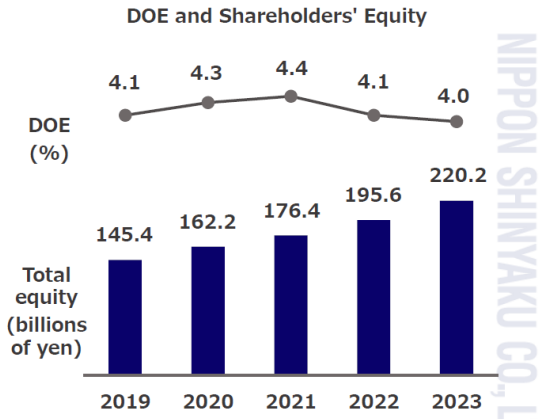
	FY2023	FY2028
Revenue	148.2 billion yen	230 billion yen
Operating profit	33.2 billion yen	30 billion yen
EPS	383 yen	341 yen
ROE	12.4%	≧ 8%
ROIC	19.3%	≧ 9%
1USD	144.6 yen	140.0 yen

In terms of management targets, we aim to achieve sales revenue of JPY230 billion, operating profit of JPY30 billion, EPS of JPY341, ROE of 8% or higher, and ROIC of 9% or higher in the final year of the plan, FY2028. On this basis, we will work to strengthen our three key themes and five management foundations to lay the foundation for becoming a company with sales of JPY300 billion in FY2030, and beyond that, a company with sales of JPY500 billion.

Shareholder Returns Policy

The Company's policy is to maintain stable dividends while taking into consideration the dividend on equity ratio (DOE).





Next is our shareholder return policy.

The Company's policy is to continue to pay stable dividends while taking into consideration the dividend on equity ratio (DOE), and to return profits to shareholders. In addition, the Company will consider the share buyback within the framework of flexible allocation.

This concludes my explanation of the 7th Medium-Term Management Plan.

Presentation Q&A on the 7th Five-Year Medium-Term Management Plan (summary)

May 28, 2024

No.	Questions	Answer.
1	I believe that the data from the global P3 trial (RACER53 study) of Viltepso is currently being analyzed. Is there heterogeneity in the impact of steroids and the improvement or decline in motor function? The global P3 trial (RACER53 study) was a global study conducted in 17 countries, so it is possible that the data may have been skewed by geographic spread. Could you share with us at this point what you have found so far?	Clinical trials 201 and 202 are to compare to the natural history of North American patients who matched to the patient population; the global P3 trial (RACER53 study) is a global trial conducted in various countries, with backgrounds such as different steroid regimens※ in each country, which we believe will increase the heterogeneity of the patient population. ※Regimen: A chronological plan of drug treatment, including the type and amount of drug, duration, and procedures.
2	If an additional clinical trial of Viltepso is required in the future, will it be designed to prevent heterogeneity, such as by narrowing the number of countries?	We would like to design a clinical trial so that there is as little heterogeneity as possible. There are already approved drugs in Japan and the U.S. For example, if we conduct a placebo-controlled clinical trial, we would like to select the countries and the facilities, taking into consideration how the patient's decision will affect enrollment.
3	Do you mean that placebo-controlled clinical trials are more difficult?	Specifically, if a placebo-controlled clinical trial is conducted in a country where approved drugs are available, patients would prefer to use them and be less willing to participate in clinical trials.
4	Regarding the global P3 trial (RACER53 study), there was no difference from placebo on the primary endpoint of Time to Stand from Supine. Are there significant differences in the other endpoints?	We cannot disclose this information at this time.
5	I understood that the results differ by country and treatment background. Is there a possibility to do subgroup analysis by region? Or have you already started?	We are planning to conduct such an analysis. Other than that, nothing can be disclosed yet at this time.

6	The global P3 trial (RACER53 study) presented that while there was a trend toward increased TTSTAND (time to rise from the floor) velocity in the active drug cohort, there was a similar trend toward increased velocity in the placebo cohort. Does this mean that the active drug cohort and the placebo cohort were compared and no improvement was seen in the active drug cohort? Or does it mean that there was a trend toward some improvement, although it did not reach statistically significance?	As announced on May 27, 2024 in the press release of Viltolarsen (NS-065/NCNP-01) for the treatment of Duchenne Muscular Dystrophy Preliminary Results of the Analysis of the global P3 trial (RACER53 study), a trend toward increased velocity was also observed in the active drug cohort, and a similar trend toward increased velocity was also observed in the placebo cohort.
7	Was there any difference in the results between the active drug cohort and the placebo cohort?	There is some difference in the results between them. Since this is before discussions with the authorities, we cannot disclose how they differ at this time.
8	As to why there was no difference between the active drug cohort and the placebo cohort in the results of the analysis, was the placebo more effective than expected or was the active drug less effective than expected?	As announced yesterday, in the global P3 trial (RACER53 study), the placebo cohort also showed a trend of increasing velocity (rise/sec) of Time to Stand from Supine. This is not the case in the natural history data from the P2 clinical trial where the velocity was decreasing. Whether this is noise in the data is still being analyzed and it is not clear whether this is a placebo effect or a steroid effect. We would like to analyze and investigate the reason why the data for the placebo group was better than expected.

9	In your analysis to date, have you identified significant differences in steroid use between the active drug cohort and the placebo cohort? Has it been confirmed to any degree at this stage that there is a difference in the percentage, type, and amount of steroids used in the active drug cohort and the placebo cohort, which leads to a difference in steroid intensity between those two cohorts? Or is this only a possible factor at this point?	We have been able to ascertain the specific steroid use for each patient and are currently analyzing the data. The protocol of the global P3 trial (RACER53 study) allows for the enrollment of patients who have been receiving steroids for more than 3 months, regardless of their method of use, but there are some discussions that 3 months may have been too short. Since steroids are effective for 6 months to 1 year, we thought that this may have been statistical noise in the global P3 trial (RACER53 study). In addition, the way steroids are used - daily or intermittent administration - varies from country to country, facility to facility, or physician to physician. The statistical noise in the global P3 trial (RACER53 study) may have been caused by the fact that the clinical trial only specified patients who had been on steroids for 3 months and did not fully take into account the duration of effect of steroids.
10	NS-089/NCNP-02 has started P1/2 clinical trial and NS-050/NCNP-03 is also about to start the trial. These clinical trials are designed to test dystrophin protein expression, not motor function. Is there a risk that steroids will affect the amount of dystrophin expression?	Steroids act on inflammation and have no effect on dystrophin expression levels because they do not act directly on dystrophin genes.

11	Do steroids boost motor function by reducing inflammation?	In the early stages, inflammation in the DMD patient's body damages the muscle, which turns muscle into fibers and fat, and his muscle is gradually wasted. Because steroids have the effect of reducing inflammation and delaying muscle loss caused by inflammation-induced fibrosis, steroids are more effective than exon skipping drugs earlier in the period when the patient's muscles are damaged and symptoms are progressing. Steroids do not continue to improve the disease, and their effectiveness gradually declines. Steroids are a good treatment in the early stages because they are very effective in slowing the loss of muscle mass. However, as the effectiveness gradually declines, other treatments are needed to support that stage.

12	PDUFA※ date of Sarepta's gene therapy drug is approaching (June 21, 2024). What do patients and doctors think about DMD treatment based on the global P3 trial (RACER53 study) results? Gene therapy is difficult to use, and the global P3 trial (RACER53 study) of Viltepso did not show good results. As a result, will the cheapest steroid be more likely to be used in the short term? Assuming that it will take about a year for the authorities to make a decision on whether or not Viltepso needs an additional clinical trial and the content of that trial, I think that it could have an impact on the sales of Viltepso. I would like to know the impact on the current year's results. ※PDUFA : A PDUFA date serves as a goal date for the U.S. FDA to make a decision about whether or not to approve new medications.	Steroids are given to most DMD patients in the U.S. In the global P3 trial (RACER53 study), Viltepso was added as a treatment for patients who were already on steroids. Please note that patients will not be switched to steroids based on the results of the global P3 trial (RACER53 study) because that they are already on steroids. We shared the information with HCPs after the global P3 trial (RACER53 study) results were released. We would like to convey the message that Viltepso is a useful drug, based on the results of the preceding clinical trial. We would like to work to make sure that the drug continues to be used in the market. In Japan, we briefed some doctors as a first report yesterday. They said safety was not a problem. It has been presented in the past at conferences and other meetings that the P1/2 clinical trial in Japan has shown a trend toward improvement in dystrophin protein expression and motor function, and that many cases have shown clinical efficacy. Therefore, we have heard from doctors that they are not going to stop immediately. At this point, we have not yet contacted a large number of physicians, so it is difficult to make a general statement, but we do not believe that Viltepso's situation will be significantly changed.
13	Regarding the global P3 trial (RACER53 study) in the US, you mentioned that steroids were used for 3 months before the clinical trial started. Are steroids usually used longer than that?	The global P3 trial (RACER53 study) enrolled patients who had already been on steroids for 3 months, and the patients would continue on steroids. At the start of the clinical trial, we thought that the effect of steroids would plateau or wane after 3 months. However, we now know that the latest paper shows that the effect lasts a little longer. Please understand that this is our assumption.

14	Is there a risk that more patients might choose gene therapy because of the results of the global P3 trial (RACER53 study)? Before the results were disclosed, we thought that Viltepso would be in a better position than gene therapy in motor function. However, the current results seem to indicate that this will not be the case any longer. What do you think will be in the labeling for Sarepta's gene therapy drug, and what do you think the likelihood of full approval is this coming June? Also, what would be your next action on these matters?	If Sarepta's gene therapy is granted full approval in June, while Viltepso was granted accelerated approval, we expect an impact, although we cannot definitively say how much. There are no patients currently receiving Viltepso who wish to switch to gene therapy. However, this is because their condition is stable on Viltepso. Regarding future patient acquisition, we believe that if Sarepta's gene therapy is fully approved, they may choose that option. However, it is known in the U.S. that there have been safety issues with gene therapy products that are now in clinical trials. When patients choose gene therapy, such risks will be taken into consideration.
15	Do you have data on the history of steroid administration for the patients in the global P3 trial (RACER53 study)? Is it possible that the data is not available and cannot be analyzed?	In each case, we have all the data on what drugs the patient is using. We know the types of drug, whether it is administered daily or intermittently.
16	The best case scenario for Viltepso would be to get full approval with a detailed analysis of the global P3 trial (RACER53 study) data. If full approval were not granted for Viltepso, would the P3 clinical trial for Europe and China also serve for the U.S.?	Depending on the results of future detailed data analysis, the best case scenario is that this data may be approved without an additional clinical trial. In the future, depending on the analysis data available and negotiations with the authorities, it will be discussed whether a new P3 trial will be conducted and which protocol and patient population will be used.
17	According to ClinicalTrials.gov※, the global P3 trial (RACER53 study) was scheduled to end in October 2023. Please explain how the announcement of the results was timed to coincide with the announcement of the 7th Medium-Term Management Plan. ※ ClinicalTrials.gov: the U.S. FDA's website and online database of clinical research studies and information about their results.	In preparation for the press release on results of the global P3 trial (RACER53 study), we had been consulting with the Japanese and U.S. authorities on the content of our disclosure. After consulting with both authorities, we were ready to disclose this content, which led to yesterday's disclosure.

18	Assuming that information sharing with the authorities began around the end of April, I assume that the date for the meeting with the FDA has already been set. Do we have a general idea of what type of meeting, such as Type-A, Type-B, will be held and when?	The authority advised us to first do a proper data analysis and then set up the meeting based on that.
19	Are you saying that the analysis to have a meeting is not ready yet, so you have not been able to approach the FDA to set a date?	Yes. After the data analysis that is currently underway is properly completed, we will discuss internally the direction of discussions with the FDA and set a date.
20	Looking back on the 6th Medium-Term Management Plan, it was unfortunate that there were delays in the trials for the exon-skipping drug, which was discovered in-house. In the 7th Medium-Term Management Plan, you are planning to speed up clinical development and improve negotiation skills with authorities. Have you already taken concrete steps or are you just getting started? Please tell us about the current situation.	We have already taken steps. We are well aware of these issues and have begun to acquire required talents, improve our ability to negotiate with the authorities, and change our decision-making structure, as explained in slides of the 7th Medium-Term Management Plan.
21	Is there a possibility of appointing medical or other specialized personnel from outside the company?	There is a possibility.
22	On page 39 of “The 7th Five-Year Medium-Term Management Plan” presentation slides, it is stated that the company plans to spend 190 billion yen on R&D as part of its cash allocation plan for the next five years. On the income statement, how much will be spent on R&D?	This R&D expense of 190 billion yen will be based on the income statement. Most of this will be for clinical trials of nucleic acid drugs, including the costs of NS-089/NCNP-02, NS-050/NCNP-03 and NS-051/NCNP-04, as well as the additional P3 trial of Viltepso.
23	If they are based on the income statement, then the 5-year cumulative R&D expenses are considerably larger than the level of R&D expenses planned for the current term. At what pace will it increase?	As you can see the product launch schedule by fiscal year on page 26, the exon skipping drugs are planned to be launched in the second half of the 7th Five-Year Medium-Term Management Plan period. A large part of R&D expenses required to launch these products will be incurred in FY2025 and FY2026.

24	As it relates to the 7th Five-Year Medium-Term Management Plan, CAP-1002 appears to be making a substantial contribution to the planned figures. I believe that Viltepso may also be included in the forecast figures, which suggest that there will be no withdrawal from the market. To what extent, if any, do you think there is a possibility that you will no longer be able to sell Viltepso in the U.S.? And what if the results of the P3 clinical trial of CAP-1002 are unfavorable?	Please understand that we cannot rule out the possibility that Viltepso will be withdrawn from the market. However, as announced yesterday, we have confirmed from the global P3 trial (RACER53 study) results that there are no safety issues with Viltepso. And although analysis is needed, we believe that if we have good data in the stratified analysis in the future, we will be able to explain that the drug is effective for a specific patient group. As I mentioned earlier the results of the P2 clinical trial, we are confident from the results of previous trials that Viltepso is a drug that is sought after by patients in need of treatment. Based on these results, we would like to proceed with negotiations with the authorities in a positive manner. If Viltepso were to withdraw from the market, the contents of the 7th Five-Year Medium-Term Management Plan would change, and the plan would have to be revised accordingly. The readout of the P3 clinical trial for CAP-1002 is scheduled for the end of this year, and Capricor Therapeutics seems to think that they will be able to manage to get the drug approved even if the trial results do not meet its primary endpoints. The authorities know that DMD is a disease area where it is difficult to verify the efficacy of drugs, as other companies and products have not been able to produce desirable results in trials. Physicians likewise have an understanding of the difficulty of validating DMD drugs. Even if the results of the P3 clinical trial of CAP-1002 are not successful, if there are data that suggest efficacy in other trials, we believe that the authorities will accept the drug based on such data. If CAP-1002 does not develop well, we will be left with no choice but to go outside and acquire a pipeline through business development or M&A.

25	In terms of the Uptravi patent expiration, I think the pediatric exclusivity will easily add six months to the Uptravi's expiration, but are you also pursuing the possibility of other extensions such as the use patent?	We have already considered this, but, as far as Uptravi is concerned, no measures have been found to extend its exclusivity.
26	The 7th Five-Year Medium-Term Management Plan seems to assume that the company will continue to be profitable even after the Uptravi exclusivity period ends. Assuming that CAP-1002 and Vyxeos are included in these projections, which products specifically will contribute the most to profits in such projected period?	CAP-1002 has a larger market because it can be used for all DMD patients regardless of the type of gene mutation. Please understand that it can be expected to be widely used in older DMD patients because it is expected to improve and maintain upper arm function and myocardium in non-ambulatory patients rather than in ambulatory patients. In this sense, we believe the drug has more potential than any of the other exon skipping drugs, which each represent a few percent of the total number of DMD patients.
27	Do the figures for CAP-1002 account for a significant portion in the 7th Five-Year Medium-Term Management Plan? Does the pediatric neurology area in the sales graph (of page 28) refer to Viltepso and CAP-1002? Are the figures for Viltepso only for Japan and the U.S.?	Slide 28 (Priority Theme I: Fostering Growth Drivers to Replace Uptravi: Image of Sales and Revenue Expansion during the 7th Medium-Term Management Plan) shows the image for each area. For Viltepso, sales forecasts for China and Europe are included in FY2028. Also, forecasted figures in FY2028 include Viltepso's revenue from Europe and China (in addition to Japan and the U.S.) and other exon-skipping drugs.
28	Does CAP-1002 have the largest amount in the revenue forecast?	Yes, it does.

29	We now understand that Capricor Therapeutics would file an application based on the results of the P2 clinical trial even if the P3 clinical trial were unsuccessful. Is there a risk that the probability of success of the P3 placebo-controlled clinical trial will be reduced due to the heterogeneity of the patient background or other reasons? Since the P2 placebo-controlled clinical trial was successful, I believe that the P3 clinical trial will also be successful. Also, as the patients get older, the noise in the data may decrease.	The P2 and P3 clinical trials have the same study design, with the P3 enrolling a larger number of patients. We, too, believed that the P3 clinical trial would be successful due to expectations for the trial's reproducibility and signed distribution agreements with Capricor Therapeutics in 2022 (for U.S. territory) and 2023 (Japan).
30	Do you think Capricor Thepeutics can handle the heterogeneity of patient backgrounds in their clinical trial?	There are a lot of factors that can cause variability in the data, but when it comes to the effect of steroids, you can say that the data is quite variable in the younger age groups, but I suspect that the factor is somewhat consistent for patients whose symptoms have progressed to the point where they are non-ambulatory.
31	How have you discussed the stock price internally? The price-to-book (PB) ratio will probably be less than 1x after this announcement. Has the Board of Directors discussed this?	At each Board meeting, the directors discuss the situation and the reasons for the weak stock price, how to increase the value of the company and how to communicate with external stakeholders. Last Friday (May 24, 2024), we passed a resolution to introduce a restricted stock compensation plan for internal directors. The introduction of such stock compensation system was a further step in our efforts to be on the same page with our shareholders in terms of share price awareness. I would like to inform you that we are taking steps and discussing the stock price through these efforts.