FY2024
Small Meeting

February 18th, 2025
Nippon Shinyaku Co., Ltd.

NIPPON SHINYAKU CO., LTD.

NIPPON SHINYAKU CO., LTD.

AGENDA

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Introduction

Toru Nakai
Representative Director, President

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Q&A

Our target for new product launch

Modified from May 27, 2024
The 7th Five-Year Medium-Term Management Plan (FY2024 - FY2028) -For Global Growth Beyond the Cliff- p.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.

Target for launching new products

Red indicates updates from the original slide of May 28th, 2024

	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 cardiomyopathy	CAP-1002 (U.S.) : DMD	NS-089/NCNP-02 (U.S.) : DMD	NS-050/NCNP-03 (U.S.) : DMD
		RGX-121 : BLA submission completed			NS-065/NCNP-01 (EU,CN) : DMD

※ AML: acute myeloid leukemia; MCL: mantle cell lymphoma; pediatric PAH: pediatric pulmonary arterial hypertension; BPDCN: blastic plasmacytoid dendritic cell tumor; SEL: systemic lupus erythematosus

ATSN-101、RGX-111
: Aiming to launch by the end of FY2028

Capital allocation

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"

cash resource	allocation		
5-year operating CF 275 billion yen (Before deduction of R&D expenses)	Investment for growth	R&D expenses 190 billion yen	Active investment to promote global development
		Capital Investment 38 billion yen	New R&D and manufacturing facilities, renovations, and digital investments in response to growth
		Flexible Allocation 100 billion yen	Licensing activities and arranging overseas bases to implement growth strategies Considering shareholder returns through acquisition of treasure stock
Cash on hand, etc. 95 billion yen	Return	Dividends 42 billion yen	Maintain stable dividends while taking into consideration the dividend on equity ratio (DOE)

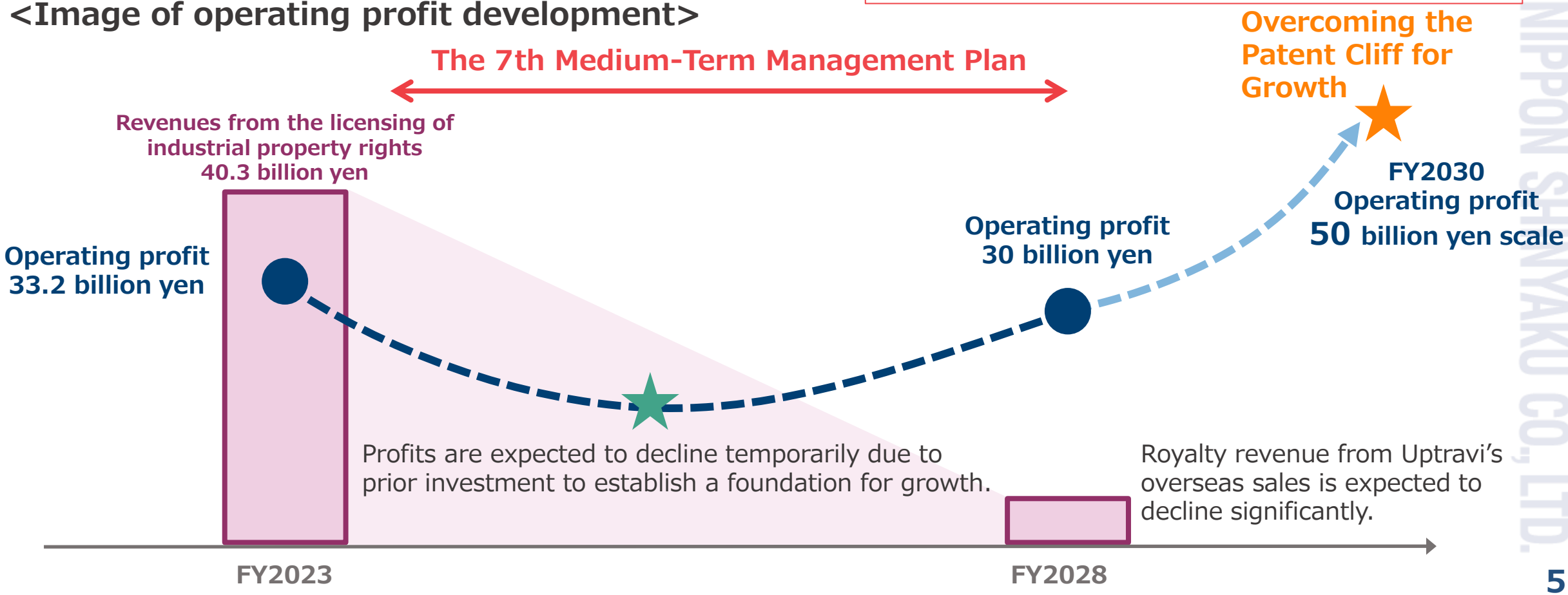
Modified from May 27, 2024
The 7th Five-Year Medium-Term Management Plan (FY2024 - FY2028)
-For Global Growth Beyond the Cliff-p.39

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.

Modified from May 27, 2024
The 7th Five-Year Medium-Term Management Plan (FY2024 - FY2028)
-For Global Growth Beyond the Cliff-p.17

<Image of operating profit development>



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- 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.

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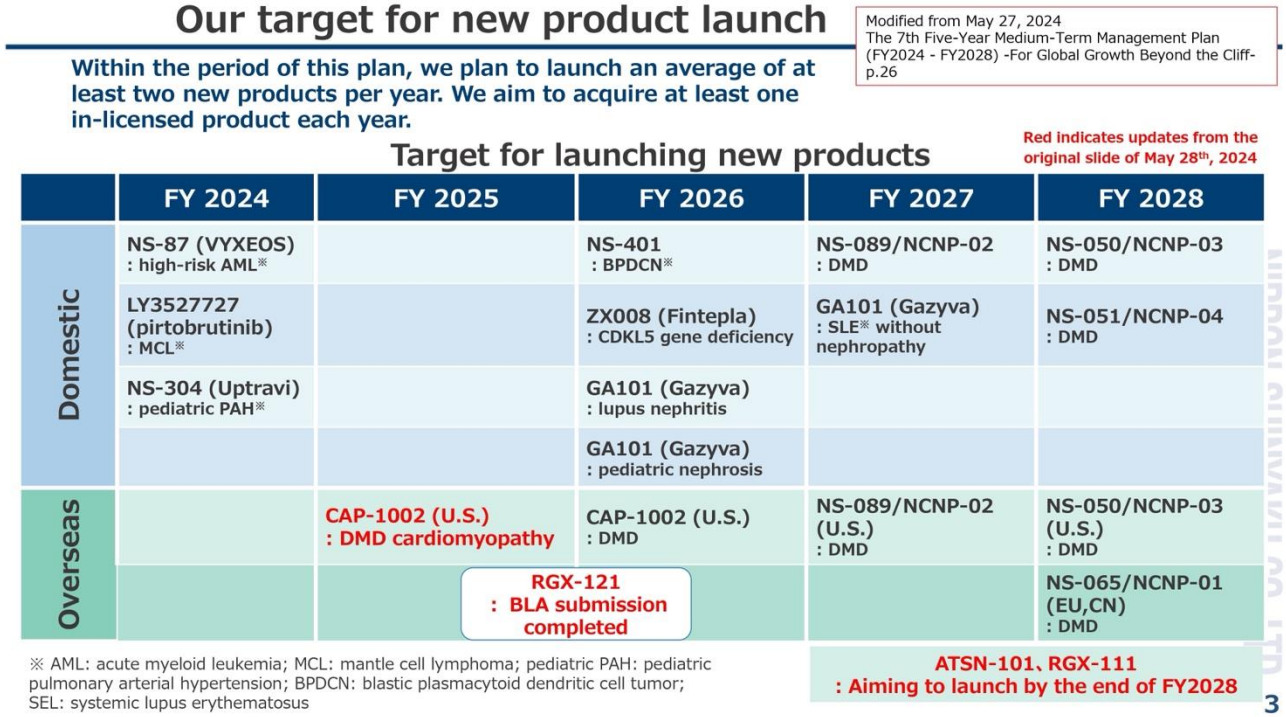
NIPPON SHINYAKU CO., LTD.

Nakai: I am Toru Nakai, President of NIPPON SHINYAKU CO., LTD. From here, we will hold a small meeting inviting sell-side analysts.

First, I will pick up some of the slides that I presented during the briefing on the Seventh Medium-Term Management Plan and explain them again, followed by a Q&A session. Thank you for your cooperation.



Our target for new product launch

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ATSN-101、RGX-111
: Aiming to launch by the end of FY2028

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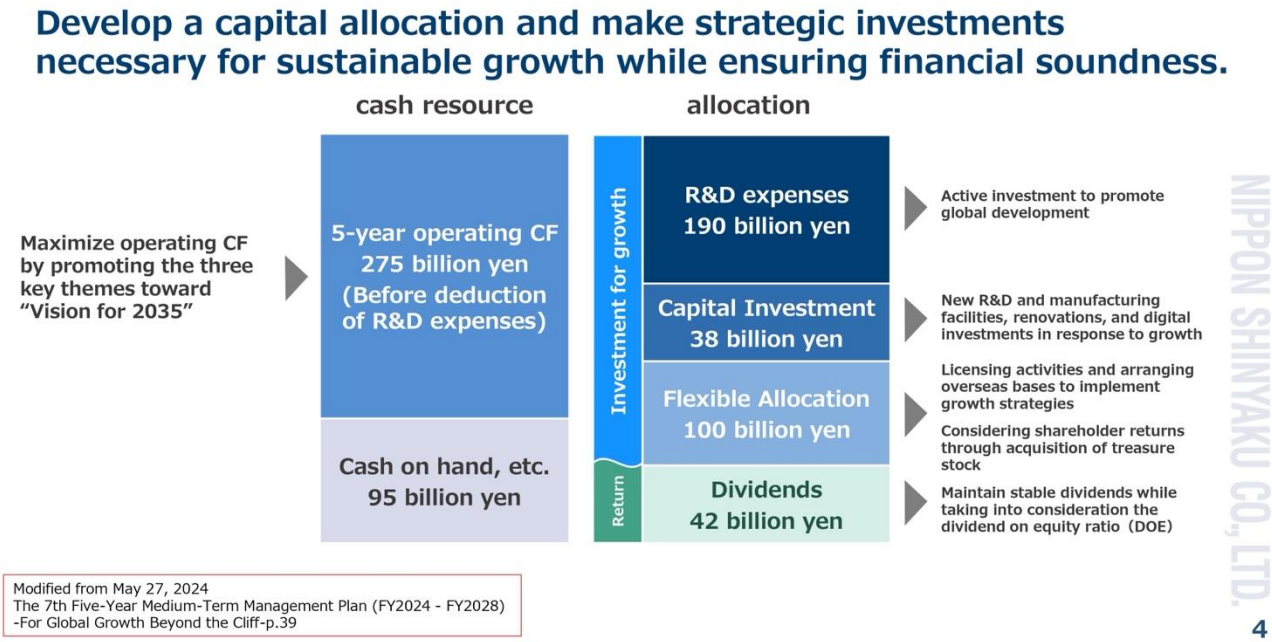
This is a table showing our annual launch targets for the Seventh Medium-Term Management Plan period. As for CAP-1002, a cell therapy drug introduced at the R&D presentation, the BLA application has been completed for the expected indication of Duchenne muscular dystrophy cardiomyopathy and we expect to launch the product within the next fiscal year. We are currently preparing the commercialization for launch.

As for other newly introduced items, ATSN-101 is under preparation for Phase III trials, and development is underway to bring it to market within the Seventh Medium-Term Management Plan period.

RGX-121 is currently in rolling BLA submission for approval in the US, and RGX-111 is in Phase I/II trials with the aim of launching it during the Seventh Medium-Term Management Plan.

As planned when we announced the Seventh Medium-Term Management Plan, we have succeeded in launching an average of at least two new products per year and acquiring at least one in-licensed product per year.

Capital allocation

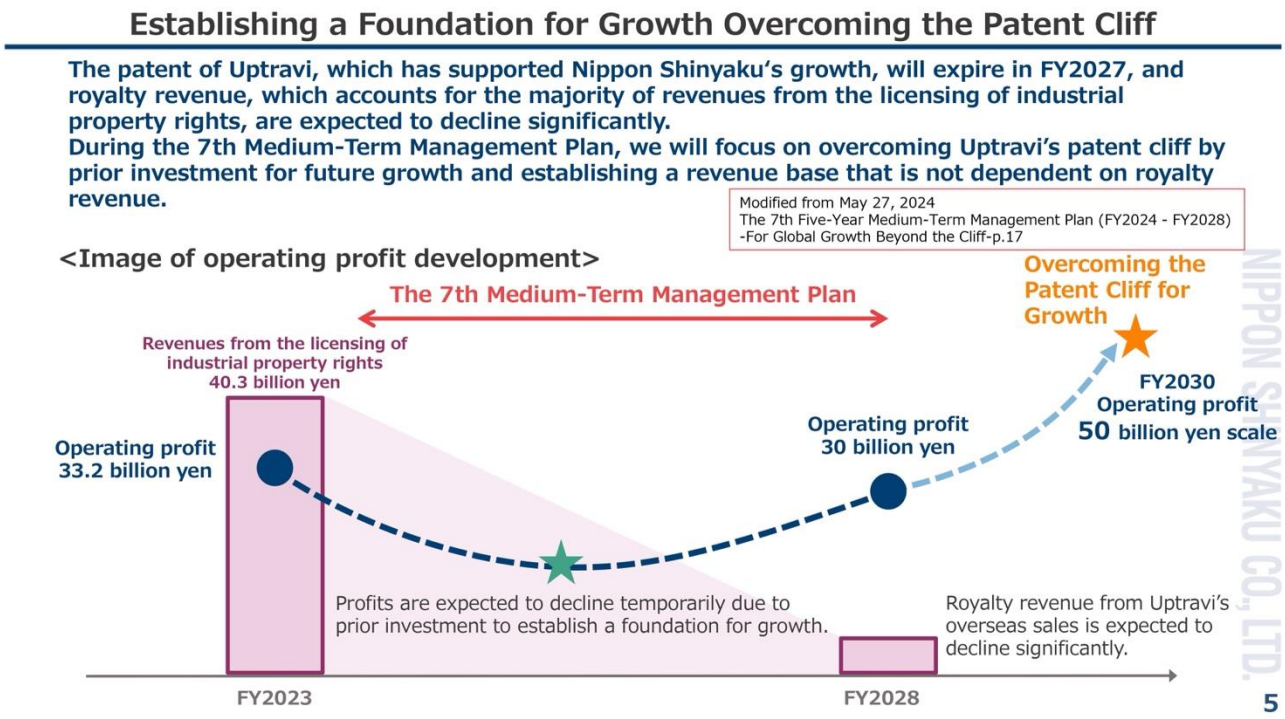


This slide shows the basic policy for capital allocation during the Seventh Medium-Term Management Plan period.

Our policy is to ensure financial soundness, including the sale of policy shareholdings and borrowing as necessary, and to aggressively make the strategic investments necessary for our sustainable growth.

We plan to invest JPY190 billion over the five years in research and development and will continue to invest aggressively in this area.

In addition, the Company has set the total amount of JPY100 billion as a flexible allocation for investment in growth, including M&A and acquisition of in-licensed products, as well as acquisition of treasury stock, and JPY42 billion as a total for shareholder returns.



Here is an image showing the transition of operating profit during the Seventh Medium-Term Management Plan period. Uptravi, which has supported our growth, will go off patent in FY2027, and royalty revenue from overseas sales of Uptravi is expected to decline significantly.

In the DMD area, we expect Viltepso to be affected by competing products in the Japanese and U.S. markets, but the situation is changing as we may be able to launch CAP-1002 earlier than expected.

Under such circumstances, we have been making investments for future growth upfront, and although profits are expected to temporarily decline in the future, we will focus on overcoming the patent cliff and establishing a revenue base that is not dependent on royalty revenue, aiming for operating profit of JPY30 billion in FY2028, and beyond that, in FY2030, we will aim for operating profit of JPY50 billion.

That's all for my explanation.

FY2024 Small Meeting for Sell-Side Analysts Q&A (summary)

February 18, 2025

No.	Question	Answer
1	You mentioned previously that you have set aside 100 billion yen as a flexible cash allocation for the 7th Five-Year Medium Term Management Plan (the MT Plan). In terms of cash flow for FY2024, intangible asset acquisitions through 3Q will total 13.1 billion yen, and if you pay $110 million to REGENXBIO as an upfront payment in 4Q, the total will be around 30 billion yen. Are you using cash early in the Plan period to acquire many in-licensing products before the Uptravi patent cliff? If this pace of in-licensing continues, what will the cash balance be?	We management team prepared for the possibility of losing in some license negotiations, but thanks to the BD（Business Development）team's efforts, we were able to win good deals beyond expectations. In the future, after our late-stage pipeline is enhanced, we will need to seek partnering opportunities for early-stage products. We will make decisions flexibly within the framework of our capital allocation as appropriate.

2	Today's presentation by President Nakai referred to the briefing on the MT Plan held in May last year, but I think there were two points where he explained that the situation was different from what was expected at the time. Could you please summarize the differences between the MT Plan that was disclosed in May last year and the current situation, from both positive and negative perspectives? The R&D expenses were only shown as a total for the five-year period, but my understanding is that the expenses will peak in FY2026 and then decrease slightly. Has that changed? Also, what is your view on the total R&D expenditure of 190 billion yen over five years? Is the probability of achieving the operating profit target increasing?	As you pointed out, we had expected that operating income would reach its lowest point around fiscal 2026 and then start to rise again. One of the points that has changed is CAP-1002, whose expected launch timing has been brought forward by one year and its expected indication has become DMD-cardiomyopathy. Originally, we forecasted sales with the assumption that CAP-1002 would be prescribed to maintain and improve upper limb function, but if it can be used to treat cardiomyopathy, it will become a product for a disease for which there are no other treatment options. Therefore, there is sufficient potential for sales to exceed the forecast in the MT Plan. The other issue is R&D trends. We had assumed that we would conduct the same type of study as Study 301 for Viltepso, but Study 303 may be slightly larger in scale and the study period may be longer. In addition, the progress of clinical trials for our other exon-skipping drugs is slightly behind schedule. As a result, R&D expenses are tending to increase more than expected. However, we expect to be able to cover the increase in R&D expenses with sales from in-licensing and other sources. Looking at the total picture, we are confident that future earnings will exceed the forecast at the time of the MT Plan's disclosure.
3	The costs will increase, but so will sales. Looking at the total picture, is it correct to say that the probability of achieving operating profits of 30 billion yen in FY2028 and 50 billion yen in FY2030 is increasing?	Your understanding is correct.
4	Regarding the progress of the MT Plan, do you think that maintaining accelerated approval for Viltepso and the launch of CAP-1002 have the potential to achieve the numerical targets for FY2028?	We are confident that it is achievable.

5	Is it achievable, including the profit margin? With Viltepso sales remaining flat, you have also acquired the exclusive development and distribution rights for RGX-121/111 in Asia, so it is expected that investment the region will be required in the future. Is the operating profit margin of 13% in FY2028 a high hurdle to achieve?	In Asia, we only have our own distribution function in China, and sales of the RGX-121/111 in Asia are not yet included in our MT forecast. We think it will take some time before we can expand into Asia.
6	When the FY2024 3Q financial results were announced, there was a message that Viltepso sales would level off. This actually means that the impact of gene therapy has appeared. Where do you think Viltepso will peak out?	The number of patients on Viltepso has increased slightly since the beginning of this fiscal year. There have been a reasonable number of new patients acquired since the start of this fiscal year, but on the other hand, there have also been patients who have lost their insurance approval, and two to three cases have switched to gene therapy. In the U.S., the number of start-form registrations for treatment with Viltepso is still increasing, and it is expected that the number of new patients will continue to increase to a certain extent, but since dropouts have been seen more than in the past since the start of this fiscal year, the overall growth is becoming flat.
7	Is the reason that the insurance has been rejected because there is only 4 years of data for Viltepso?	This is not because there is only 4 years of data, but rather the result of reimbursement decisions being made in light of the circumstances of individual patients and payers' policies. For example, payers with a policy of seeking to meet certain criteria in the six-minute walk test do not reimburse Viltepso for non-ambulatory patients, so there are cases where patients do not receive insurance reimbursement as their condition progresses. Even so, patients who still wish to receive treatment with Viltepso have switched from private insurance to Medicaid and have made the decision to continue with Viltepso.

8	In Japan, the number of patients with Viltepso has already reached a plateau, but if gene therapy becomes available, the number of patients with Viltepso may decrease slightly again. On the other hand, it may be too early for the number of patients with Viltepso in the U.S. to reach a plateau. Will it reach a plateau from FY2025?	I personally think that sales could be increased a little more. NS Pharma's (NSP) commercial team has also started to focus on preparations for the launch of CAP-1002, and this may have slowed down the pace of activity for Viltepso. As the pace of new patient registrations has picked up since the end of last year, I think that sales could still increase if NSP controls the focus on Viltepso.
9	Regarding the maintenance of accelerated approval for Viltepso, if it is decided to withdraw from the market at the Type C Meeting in April, the impact will be significant. From your comments, I think that accelerated approval can be maintained. Could you please provide a rational, convincing, and confident explanation of why the status can be maintained?	We were planning to hold a Type C Meeting in October last year, and had submitted a briefing document to the FDA in advance. The contents were a summary of the results of Study 301 and a brief outline of the protocol for Study 303. We received a response from the FDA in advance, which said that they would like to see the Clinical Study Report, which includes the complete data set for Study 301, and that, based on the briefing document, the protocol for Study 303 seemed reasonable, but that in order to make a judgment, they would need the full data set for Study 301 and the full protocol for Study 303. In other words, the FDA has said that our simplified approach is reasonable. Based on this, we believe that the FDA does not feel that our approach is negative.
10	If Study 301 is approved and shows some potential, I think it will depend on the protocol for Study 303. I'm also wondering whether Study 301 will be evaluated. Is that going to be okay?	Study 301 is the first completed P3 clinical trial in the field of DMD. It is likely to be evaluated as valuable data because it has been properly collected for one year, including placebo data.
11	Has your view that the increase in dystrophin as a biomarker is significant still not changed?	Our position on this has not changed, as accelerated approval is sometimes granted for surrogate endpoints for drugs from other companies.
12	Will the full protocol for Study 303 be submitted on schedule?	We are hoping to submit it by the end of February, or at the latest, the beginning of March.
13	Has the FDA given any response to the Clinical Study Report that was submitted last December? Do you usually have to wait 2-3 months after submission?	At the moment, we think the FDA is still analyzing the data.

14	What was the reaction of the DMD specialists in the U.S. when President Nakai met with during his business trip there? What about the intention to continue treatment in light of the FDA full approval of Sarepta's gene therapy drug Elevidys and the announcement of the results of Study 301 for Viltepso? Did Mr. Nakai hear the opinions of the physicians prescribing Elevidys?	Physicians who are prescribing Viltepso seem to be thinking about the results of Study 301 separately from their own experiences of its effectiveness in clinical practice. For that reason, there has been no dramatic decrease in prescriptions of Viltepso following the publication of the study results. According to the disclosures from Sarepta, the number of patients receiving Elevidys appears to be increasing, but I have heard that there are also cases where physicians consider treatment at the request of patients or family members, who have expectations that “gene therapy will cure the disease in a single treatment”.
15	You explained earlier that, although the effects of gene therapy are starting to be seen in some cases, it is still possible to increase sales of Viltepso a little more. The number of patients for your other exon-skipping drugs under development is decreasing compared to the original plan, and it seems difficult to achieve the sales you originally envisioned, so there may be room for discussion regarding the continuation of their development. I think you originally considered out-licensing of Viltepso as a post-approval option, but you have started distributing the product yourself and are seeing results. On the other hand, the emergence of Sarepta's gene therapy Elevidys is changing the competitive situation in the DMD field, and if other competitors launch new products in the future, the situation will change again. Are you going to continue development on your own in the future? You plan to spend 190 billion yen over five years on R&D, but that is a small amount compared to Sarepta, which is focusing on the U.S market. Can you achieve sustainable growth in the future with your current R&D strategy?	As you have pointed out, the current situation regarding PMO (Phosphorodimidate morpholino Oligomers) and exon-skipping drugs is changing. The test results for the competing products to Avidity's NS-089 are coming out. On the other hand, it seems that two serious adverse events have been reported. We are also paying close attention to the development status and approval potential of individual competing products. In addition, there is a gene therapy called Elevidys in the DMD market, and we are discussing how we will develop in the DMD field at our board meetings on a regular basis. In terms of collaboration with other companies, Capricor presented at a conference on a new approach for exosome-based PMO delivery, and we are considering research into DDS (Drug Delivery System) that adds something to PMO. In addition to Capricor, we are also keeping an eye on the trends of other academia and venture companies. I think that the timing is a little late to partner with large pharmas with just the PMO we are developing now, but if we develop a new product that adds something to the PMO, partnering with other companies is a viable option. When we find a new possibility, we will think carefully about whether it would be faster to develop it in-house or in partnership with other companies.

16	Can you change your R&D strategy flexibly in response to future developments, while keeping an eye on Sarepta's moves?	We will think in a flexible, dynamic way.
17	Why do you think Sarepta has stopped developing exon-skipping drugs? Is it a judgment about the future potential of the modality, or a commercial message to focus on Elevidys?	Conventionally, exon-skipping drugs or gene therapy drugs are first approved for accelerated approval and then undergo P3 trials after launch. However, the FDA did not allow Sarepta's PPMO to proceed in the same way due to safety concerns. This may have been one of the main reasons for them to discontinue development. The FDA evaluates the safety of PMOs and has determined that they can be sold on the market using surrogate endpoints. However, we think that the FDA is taking a strict stance on accelerated approval for products that raise safety concerns. In the future, if we are to proceed with development using new technologies other than PMO, we will be able to follow the same pathway as before if safety can be confirmed. Otherwise, we will move flexibly, targeting different diseases, etc.

18	Through pre-marketing activities, did you understand the number of patients waiting for CAP-1002 in the U.S.?	We plan to disclose sales and expenses forecasts at the appropriate time in the future. We conducted a survey of U.S. payers regarding their willingness to reimburse CAP-1002 and their pricing sensitivity. Depending on the number of patients assumed by the payer, there is strong willingness to reimburse if the annual drug cost is similar to that of Viltepso. This is a supplementary response to the question I received from another analyst at the R&D Meeting earlier today. We have a sense that the number of patients who will be administered the drug will be around 35% to 55% LVEF (left ventricular ejection fraction), and we are currently investigating the exact number of patients. We believe that patients with an LVEF of 35% or less are too far along in their condition to be treated, and that patients with an LVEF of over 55% are close to being normal people and will have difficulty in an insurance reimbursement. In addition, we are working to establish logistics, including the certification of medical institutions that can handle the ultra-cold chain for CAP-1002, a frozen drug in a vial. We believe that this will enable us to predict the number of target patients more accurately.
19	How many patients are waiting for CAP-1002?	The base is the more than 100 patients currently participating in the clinical trials, and we already know which medical facilities they are scheduled to be treated at. The remaining potential is how to approach DMD patients with cardiac symptoms. In addition to pediatric neurologists, who are the target of Viltepso, we are currently investigating and considering field activities for pediatric cardiologists.
20	After its launch, Elevidys was used by many patients who had been waiting for it, and after it had settled down, it increased again in the most recent quarter. Is the same trend expected for CAP-1002 sales?	Since there is currently no treatment for cardiomyopathy, it will depend on how many potential patients we can find in addition to the more than 100 patients currently participating in the clinical trials.

21	I would like to ask about the HOPE-3 study for CAP-1002. Since the bioequivalence of the drugs at the manufacturing facilities in Los Angeles and San Diego was proven in the non-clinical study, is the aim of HOPE-3 study cohort B to expand the number of subjects by combining it with cohort A, rather than to prove bioequivalence?	You are right. They are proceeding with the test by simply increasing the number of subjects.
22	In the past, you have explained that some payers reimburse for both Viltepso and gene therapy, but what is the current reimbursement trend among payers? At the moment, there are very few patients who use both, so it is still difficult to grasp the thinking of payers. At today's R&D Meeting, you mentioned the possibility of combining gene therapy and enzyme replacement therapy in the treatment of mucopolysaccharidosis. I personally think that reimbursement will be difficult without evidence of combined therapy.	Last year, I explained that there are several payers who have a policy of reimbursing exon-skipping drugs even in cases where the patient's condition worsens after gene therapy has been administered, in the absence of data on the combined use of exon-skipping drugs and gene therapy. As you say, it's been less than a year since the gene therapy was launched, and there are no patients who have become worse after receiving the treatment and want to use the exon-skipping drug. For that reason, there are no patients who meet those policies at the moment. There is probably a view among payers that it is difficult to reimburse without data. On the other hand, in this area of rare pediatric diseases, some payers will allow combination therapy from a humanitarian or ethical perspective if there are no safety issues. Although the combination therapy did not pass the pre-approval screening, it was actually reimbursed after negotiations with physicians. Changing the subject, since patients using other modalities are also included in the clinical trials for CAP-1002, payers will probably be more likely to approve combination therapy.
23	Is there a growing understanding among many patients that gene therapy and exon-skipping drugs can be used in combination?	That is correct.

24	Can the same be said about mucopolysaccharidosis?	In the treatment of Mucopolysaccharidosis, we aim to have patients become enzyme replacement therapy-free by having them use the gene therapy RGX-121/111 before enzyme replacement therapy. By showing data in the future of patients who were on enzyme replacement therapy becoming enzyme replacement therapy-free after being administered RGX-121, we believe that payers will reflect the order and use of the two therapies in their policies.
25	RGX-121/111 is administered into the brain. What is the mechanism by which enzyme replacement therapy becomes unnecessary?	Although RGX-121/111 is administered locally, it does not remain completely within the brain, but exits the brain slightly. As a result, enzymes are produced outside the brain and central nervous system.
26	You explained at the R&D Meeting earlier today that you had acquired several gene therapy products, but that you wanted to work on the central nervous system next, and that you had chosen a product that works on the central nervous system locally because you wanted to learn about CMC（Chemistry, Manufacturing and Control）. How much revenue do you expect from each product? And do you have a comprehensive sales strategy in place, including marketing? For example, early treatment is desirable for mucopolysaccharidosis, but I assume that you will need to spend a certain amount on marketing to cover the whole of the U.S., including things like where newborn screening tests are provided.	We expect even more from ATSN-101, as it is used for a slightly larger patient population than Luxturna (which has annual sales of around $50 million in the U.S.), which is used for a similar disease. As stated in the REGENXBIO materials, the estimated number of patients with Mucopolysaccharidosis Type II (RGX-121) is 500 in the U.S. and 165 in Japan. The sales of competing products in the U.S. are $196 million for Elaprase (enzyme replacement therapy for Mucopolysaccharidosis type II) and $71 million for Aldurazyme (enzyme replacement therapy for Mucopolysaccharidosis type I), but RGX-121/111 is an opportunity that has the potential to replace enzyme replacement therapy with the possibility of early administration, and we will invest in appropriate promotional activities and commercial forces.
27	In some cases, enzyme replacement therapy may be sufficient for patients with mild symptoms, and RGX-121/111 is highly invasive due to its direct administration to the brain. The number of patients who could be targeted may be lower than the estimated number of patients.	Considering the severity of the disease and the competitive situation, we do not believe that all patients will be eligible for treatment. We are currently analyzing the data to see whether the number of eligible patients is around half of the 500 patients, and we will provide further information when we announce our sales guidance.

28	I would like to ask about insurance reimbursement. I heard about a case where insurance reimbursement was rejected for a patient who had lost ambulation and was being treated with Viltepso. In a disease where early treatment is desired, the expected effects of gene therapy are seen as limited in a condition where symptoms have progressed to the point of being 4 to 6 years old, so is there any chance of insurance reimbursement? In the U.S., where there is a growing debate over medical costs, how will you proceed with measures for insurance reimbursement as the launch date approaches? If there are any discussions with patient advocacy groups or payers, I would like to know about them.	Patients in the P1/2/3 clinical study for RGX-121 are between 4 months and 5 years old. Mucopolysaccharidosis type II is now being included in newborn screening in some areas of the U.S., and it is thought that definitive diagnoses will be made more quickly in the future.
29	Do you include gene therapy as a modality that can be used for AI drug discovery? At the R&D briefing earlier, you said that one product had advanced to the preclinical stage in the neuromuscular disease area and one in the hematological cancer area. How long will it be before you have products in the preclinical stage?	AI drug discovery requires a large amount of data, and is mainly used for small-molecule drugs, while the amount of data for gene therapy is still insufficient. The amount of data is also limited in our core area of rare diseases, but we are expecting two products per year. We are prioritizing speed over quantity.