Nippon Shinyaku Co., Ltd.

FY2025/Q3 Earnings Call and Presentation

February 9, 2026

Event Summary

[Company Name]	Nippon Shinyaku Co., Ltd.
[Event Type]	Earnings Announcement
[Event Name]	FY2025/Q3 Earnings Call and Presentation
[Date]	February 9, 2026
[Number of Speakers]	6

Toru Nakai	Representative Director, President
Takanori Edamitsu	Director, Business Management & Sustainability
Kazuyuki Iwata	Director, Sales and Marketing
Keiichi Kuwano	Director, Research & Development
Manabu Beppu	Corporate Officer, Head of R&D Planning and Administration Div.
Hideyasu Takechi	Corporate Officer, Department Manager, Corporate Planning Dept.

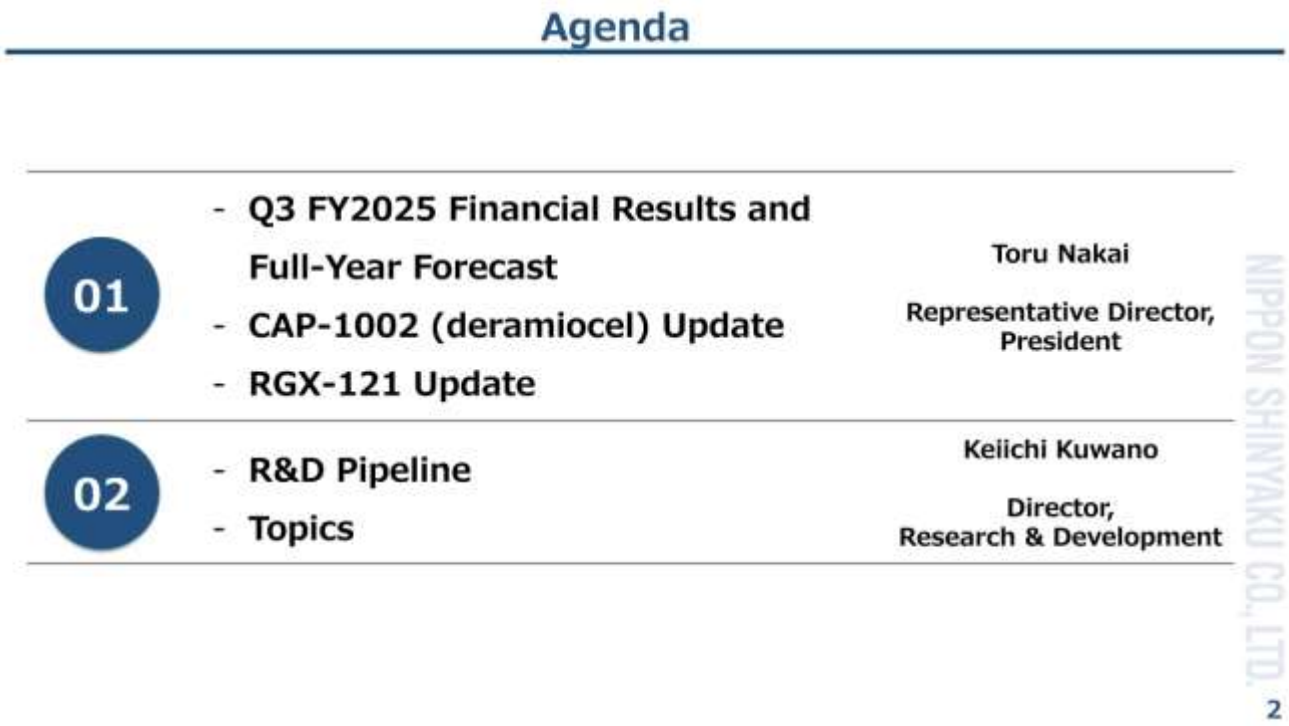
Presentation

Takechi: Now it is time to begin the financial results briefing of Nippon Shinyaku Co., Ltd. for Q3 of FY2025.

To begin with, I would like to introduce attendees from our company. This is Nakai, Representative Director, President. This is Edamitsu, Director, Business Management & Sustainability. This is Iwata, Director, Sales and Marketing. This is Kuwano, Director, Research & Development. The moderator is Takechi from Corporate Planning Department. Thank you.

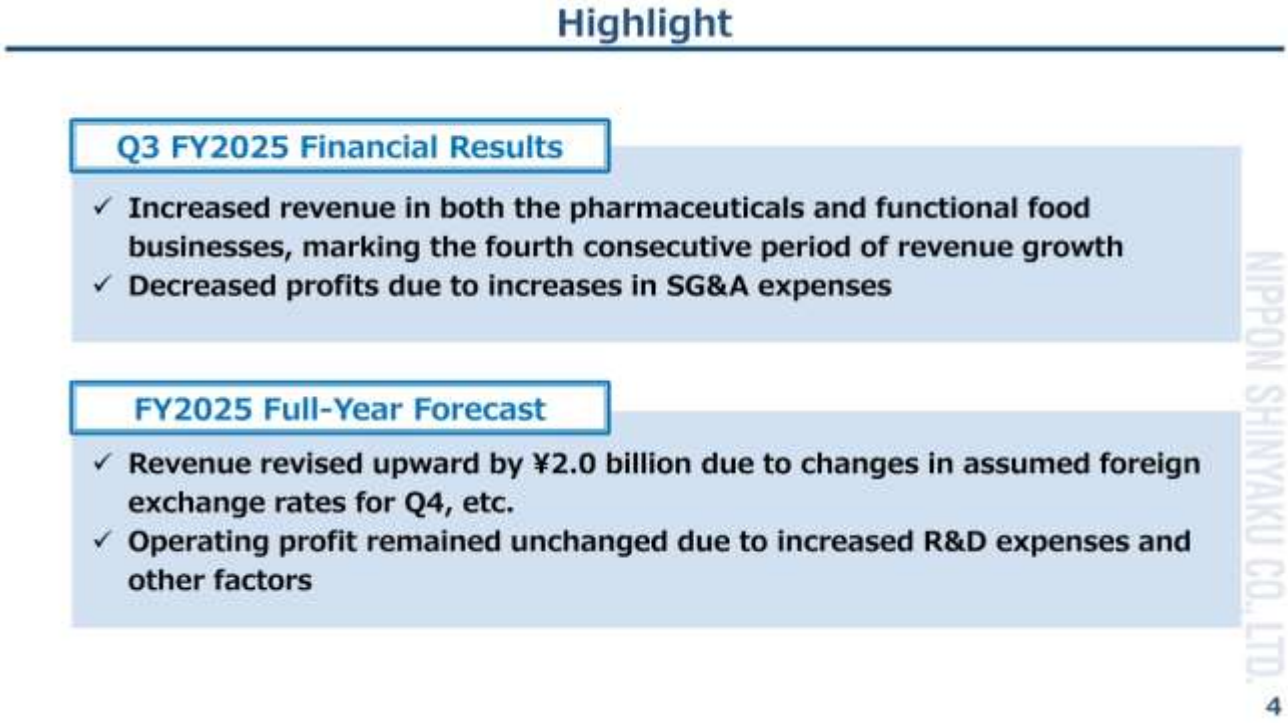
The content of this presentation will be available on our website as an on-demand video streaming and transcript, so please be aware of this when asking questions after the presentation.

Now, Mr. Nakai, please start.



Nakai: I am Toru Nakai, President of Nippon Shinyaku. Thank you very much for taking time out of your busy schedules to join our financial results briefing for Q3 of FY2025 today.

Today, I will discuss our financial results of Q3 of FY2025 and our forecast for FY2025, as well as updates on CAP-1002 and RGX-121. After that, Mr. Kuwano, who is in charge of research and development, will explain the R&D pipeline and topics.



Then, I will explain the financial results of Q3 of FY2025 and the forecast for FY2025. First, I would like to share with you some key points from today's financial results presentation.

In Q3 of FY2025, both the pharmaceuticals and functional food businesses reported an increase in revenue, marking the fourth consecutive period of revenue growth. Operating profit decreased mainly due to an increase in SG&A expenses.

The forecast for FY2025 has been revised upward by JPY2 billion for revenue due to a change in the assumed exchange rate for Q4 and other factors, but there is no change in operating profit due to an increase in R&D expenses and other factors.

Q3 (Apr - Dec) FY2025 Summary

- **Increased revenue in both the pharmaceuticals and functional food businesses, marking the fourth consecutive period of revenue growth**
- **Increased SG&A expenses led to a decline in both operating profit and profit attributable to owners of parent**

(million yen)	Q3 FY2024		Q3 FY2025		YoY	
	actual	ratio	actual	ratio	change	%
Revenue	121,320	100.0%	127,135	100.0%	+5,815	+4.8%
(Pharmaceuticals)	(104,560)	(86.2%)	(110,194)	(86.7%)	(+5,633)	(+5.4%)
(Functional Food)	(16,759)	(13.8%)	(16,941)	(13.3%)	(+182)	(+1.1%)
Cost of sales	38,810	32.0%	42,011	33.0%	+3,201	+8.2%
SG&A expenses	27,562	22.7%	31,704	24.9%	+4,141	+15.0%
R&D expenses	23,547	19.4%	23,033	18.1%	-514	-2.2%
Other income	1,725	1.4%	2,298	1.8%	+573	+33.3%
(Foreign exchange gain)	(1,058)	(0.9%)	(1,742)	(1.4%)	(+683)	(+64.6%)
Other expenses	371	0.3%	351	0.4%	-20	-5.5%
Operating profit	32,752	27.0%	32,333	25.4%	-419	-1.3%
Finance income	774	0.6%	1,014	0.8%	+239	+31.0%
Finance costs	89	0.1%	120	0.1%	+31	+35.3%
Profit before tax	33,438	27.6%	33,227	26.1%	-210	-0.6%
Income tax expense, etc.	4,885	4.0%	7,382	5.8%	+2,496	+51.1%
Profit attributable to owners of parent	28,552	23.5%	25,844	20.3%	-2,707	-9.5%

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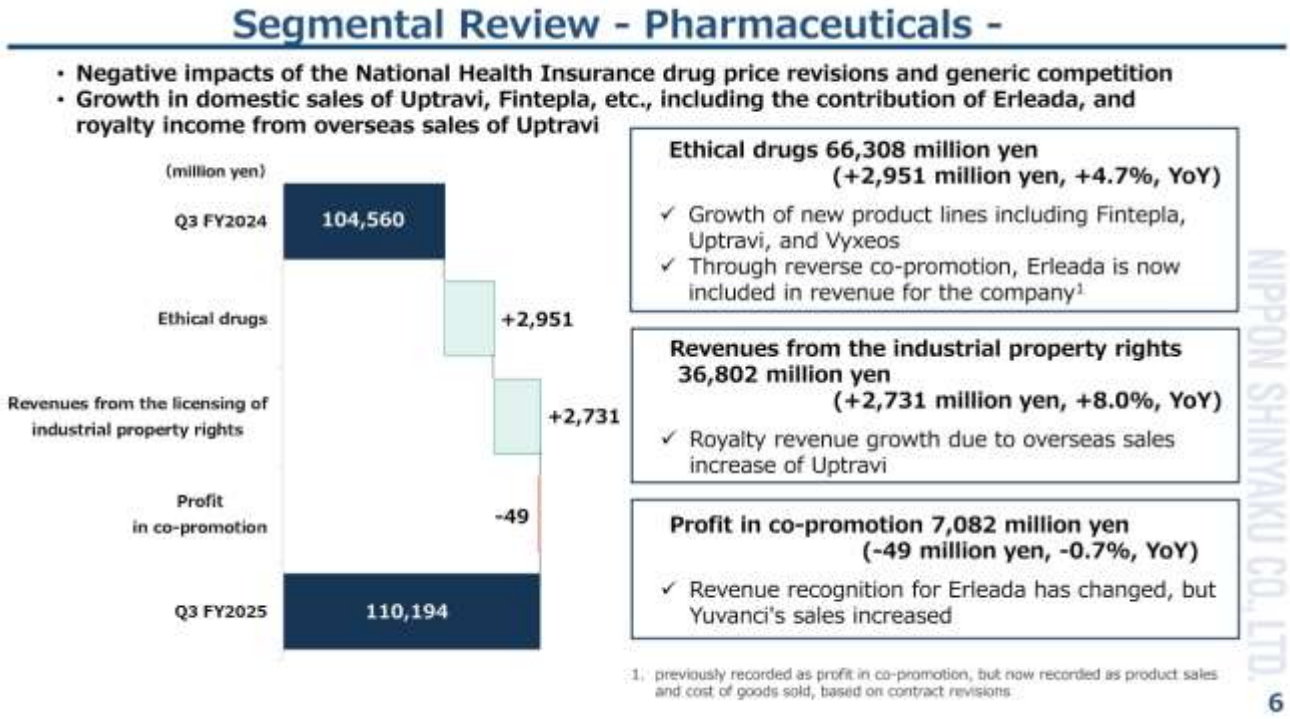
Let me explain in detail from here. Please take a look at slide five.

As a summary of the results of Q3 of FY2025, on a YoY basis, consolidated revenue increased by JPY5,815 million to JPY127,135 million, operating profit decreased by JPY419 million to JPY32,333 million, and profit before tax decreased by JPY210 million to JPY33,227 million.

With respect to income tax expense, the income tax rate decreased in FY2024 due to the recognition of the recoverability of deferred tax assets in NS Pharma, but this has no impact this fiscal year, resulting in an increase in income tax expense, etc.

As a result, profit attributable to owners of parent decreased by JPY2,707 million to JPY25,844 million.



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In the pharmaceuticals business, despite the effects of the National Health Insurance drug price revisions and generic competition, consolidated revenue increased by 5.4% YoY to JPY110,194 million, thanks to growth in domestic sales of Uptravi, royalty income from overseas sales of the same product, and growth of new product lines such as Fintepla and Vyxeos, as well as the contribution of Erleada, which has been recorded as sales of the Company since October last year based on contract revisions.

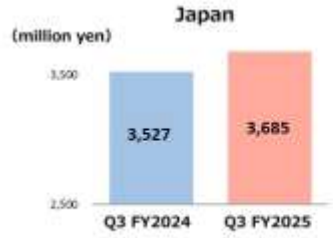
Sales Trends of Viltepso® (viltolarsen)

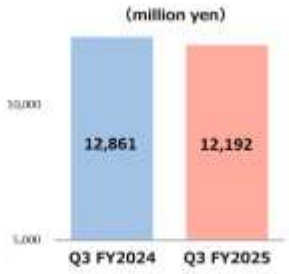
- **Sales of Viltepso in the U.S. declined YoY in Q3 FY2025**
- **The average dose per patient has decreased due to younger patient population**

(million yen)	Q3 FY2024 actual	Q3 FY2025 actual	YoY change	YoY %	FY2025 forecast	Notes on Q3 FY2025 results
Japan	3,527	3,685	+157	+4.5%	4,800	✓ The number of patients currently on therapy with Viltepso is more than three-quarters of the peak number of 128 patients in the data from Chuikyo[1]. ✓ Promoting early diagnosis and intervention for younger patients
US	12,861	12,192	-669	-5.2%	16,400	✓ Insurance reauthorizations became stricter after launch of multiple DMD treatment options.
(million US$)	(84.30)	(81.97)	(-2.33)	(-2.8%)	(110.02)	✓ The average dose per patient has decreased due to younger patient population
Total	16,389	15,877	-512	-3.1%	21,200	

1. Central Social Insurance Medical Council

Exchange rates	Q3 FY2024 actual	Q3 FY2025 actual	4Q FY2025 assumption
USDJPY	152.6	148.7	150.0





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Please turn to slide seven.

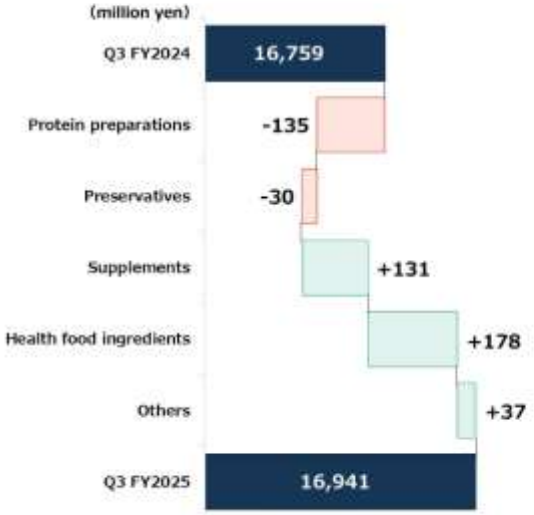
Here we show the sales of Viltepso, which is sold in Japan and the United States.

Sales results of Q3 of FY2025 were JPY3,685 million in Japan and JPY12,192 million in the United States. In the US, the sales in dollar terms also decreased YoY. Although new patients continue to be acquired, the number of patients dropping out of the program is increasing due to the launch of several high-cost therapies on the market, which has resulted in stricter insurance reauthorizations.

For the full year of FY2025, we expect sales of JPY4.8 billion in Japan and JPY16.4 billion in the US.

Segmental Review - Functional Food -

- **Sales decline in protein preparations and preservatives due to competitive market**
- **Growing health food ingredients amid rising demand for beauty-related products, and solid growth of supplements helped by the market expansion**



Protein preparations 10,420 million yen
(-135 million yen, -1.3%, YoY)
- ✓ Sales prices decline of protein preparations for the processed food industry
- ✓ Decrease in demand due to customers switching to cheaper raw materials

Preservatives 2,546 million yen
(-30 million yen, -1.2%, YoY)
- ✓ Rising prices have led to consumers holding back on purchases, resulting in a decrease in user output.

Supplements 2,025 million yen
(+131 million yen, +7.0%, YoY)
- ✓ Sales increase in both athletes and anti-aging care category

Health food ingredients 927 million yen
(+178 million yen, + 23.8%, YoY)
- ✓ Expanded demand for beauty-related products

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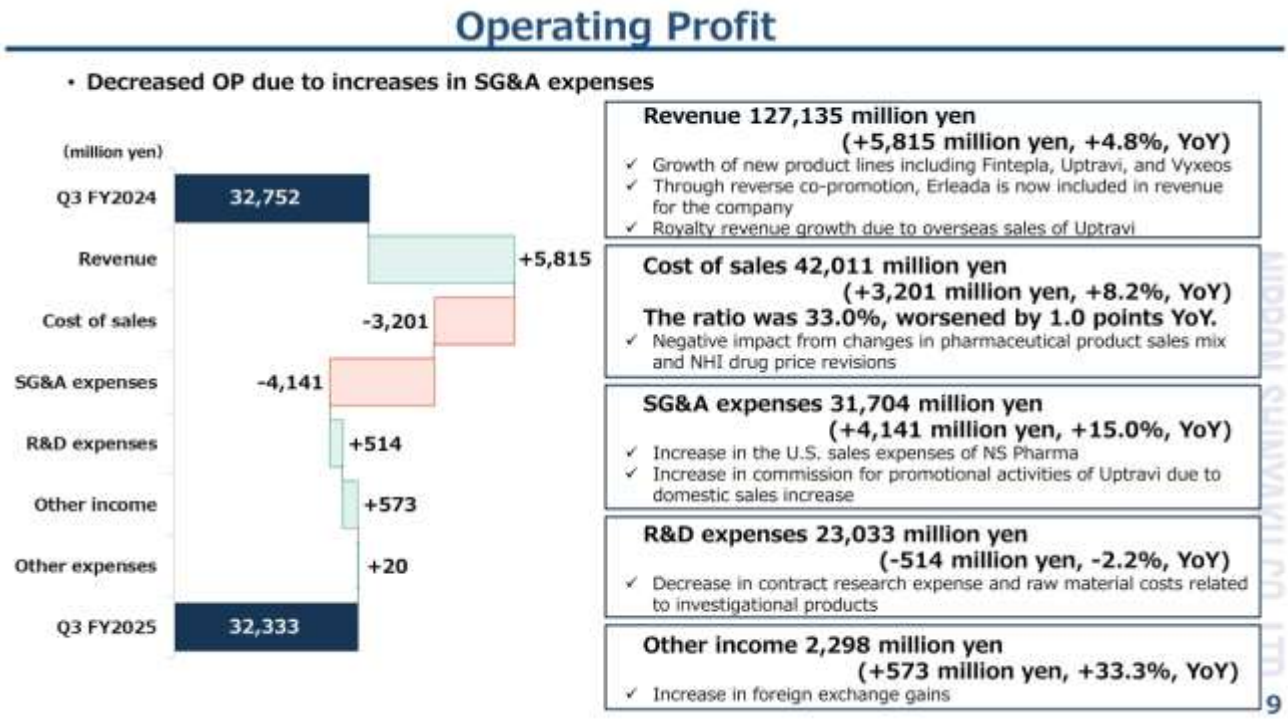
Please turn to slide eight.

In the functional food business, sales of protein preparations and preservatives declined due to the severe market environment, but sales of health food ingredients and supplements increased, resulting in consolidated revenue of JPY16,941 million, up 1.1% YoY.



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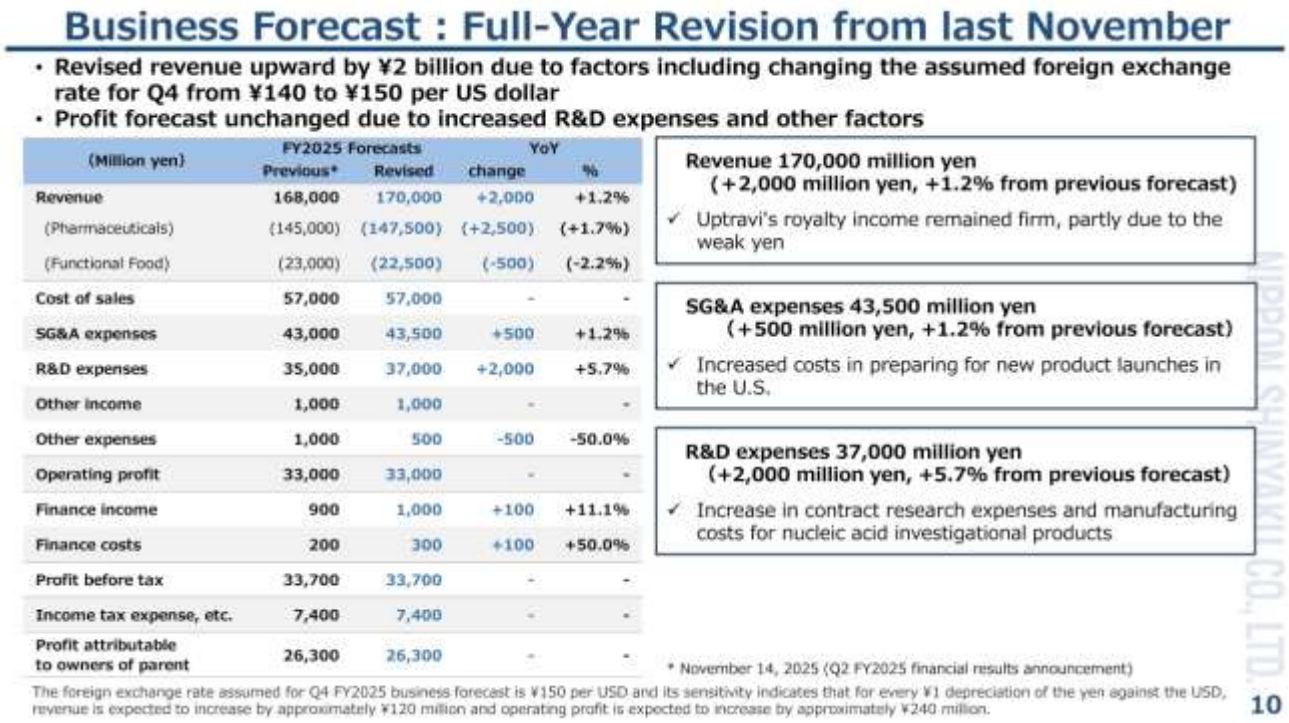
Next, in terms of cost of sales, the cost of sales ratio worsened by 1 percentage point YoY to 33%, mainly due to the sales mix and the impact of NHI drug price revisions.

SG&A expenses increased by 15% YoY to JPY31,704 million, mainly due to an increase in sales expenses at NS Pharma in preparation for the new product launches.

R&D expenses amounted to JPY23,033 million, down 2.2% YoY, mainly due to a decrease in contract research expense and raw material costs related to investigational products. As for other income, foreign exchange gains increased.

As a result, operating profit was JPY32,333 million, down 1.3% YoY.



Please turn to slide 10.

Next, I will explain the business forecast for FY2025.

Here we show the difference between the revised forecast and the previous forecast. Consolidated revenue is expected to be JPY170 billion, JPY2 billion higher than the previous forecast, mainly due to the change in the assumed exchange rate for Q4 from JPY140 to JPY150 per US dollar.

SG&A expenses are expected to increase by JPY0.5 billion to JPY43.5 billion due to an expected increase in expenses in preparation for new product launches in the United States.

R&D expenses are expected to increase by JPY2 billion to JPY37 billion due to an increase in contract research expenses and manufacturing costs for nucleic acid investigational products. There will be no change in operating profit and other respective profit.

Revised Business Forecast for FY2025 (consolidated)

(million yen)	FY2024 actual	FY2024 ratio	FY2025 forecast	FY2025 ratio	YoY change	YoY %
Revenue	160,232	100.0%	170,000	100.0%	+9,767	+6.1%
(Pharmaceuticals)	(138,654)	(86.5%)	(147,500)	(86.8%)	(+8,845)	(+6.4%)
(Functional Food)	(21,577)	(13.5%)	(22,500)	(13.2%)	(+922)	(+4.3%)
Cost of sales	51,116	31.9%	57,000	33.5%	+5,883	+11.5%
SG&A expenses	38,011	23.7%	43,500	25.6%	+5,488	+14.4%
R&D expenses	34,341	21.4%	37,000	21.8%	+2,658	+7.7%
Other income	874	0.5%	1,000	0.6%	+125	+14.3%
Other expenses	2,186	1.4%	500	0.3%	-1,686	-77.1%
Operating profit	35,450	22.1%	33,000	19.4%	-2,450	-6.9%
Finance income	830	0.5%	1,000	0.6%	+169	+20.4%
Finance costs	145	0.0%	300	0.2%	+154	+106.3%
Profit before tax	36,135	22.6%	33,700	19.8%	-2,435	-6.7%
Income tax expense, etc.	3,577	2.3%	7,400	4.4%	+3,822	+106.9%
Profit attributable to owners of parent	32,558	20.3%	26,300	15.5%	-6,258	-19.2%

Foreign exchange rates (USDJPY)

Q3 FY2024 actual	Q3 FY2025 actual	4Q FY2025 assumption
152.6	148.7	150.0

The foreign exchange rate assumed for Q4 FY2025 business forecast is ¥150 per USD and its sensitivity indicates that for every ¥1 depreciation of the yen against the USD, revenue is expected to increase by approximately ¥120 million and operating profit is expected to increase by approximately ¥240 million.

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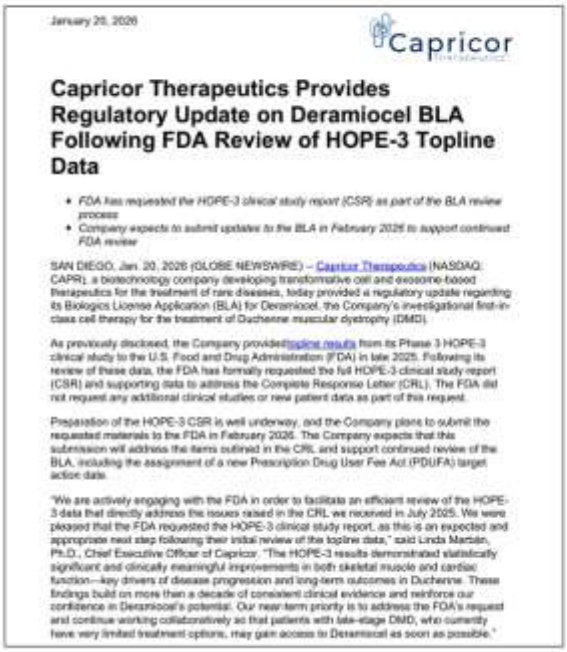
Please turn to slide 11.

Next, I will explain the revised forecast compared to the results of FY2024.

Revenue is expected to be JPY170 billion, an increase of 6.1% YoY. As for cost of sales, the cost of sales ratio is expected to deteriorate by 1.6 percentage points to 33.5%. SG&A expenses are expected to increase by 14.4% to JPY43.5 billion, and R&D expenses are expected to increase by 7.7% to JPY37 billion.

As a result, operating profit is expected to decrease by 6.9% to JPY33 billion, profit before tax by 6.7% to JPY33.7 billion, and profit attributable to owners of parent by 19.2% to JPY26.3 billion.

CAP-1002 (deramiocel) : Regulatory Update



January 20, 2026

Capricor

Capricor Therapeutics Provides Regulatory Update on Deramiocel BLA Following FDA Review of HOPE-3 Topline Data

- *FDA has requested the HOPE-3 clinical study report (CSR) as part of the BLA review process*
- *Company expects to submit updates to the BLA in February 2026 to support continued FDA review*

SAN DIEGO, Jan. 20, 2026 (GLOBE NEWSWIRE) -- Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company developing transformative cell and exosome-based therapeutics for the treatment of rare diseases, today provided a regulatory update regarding its Biologics License Application (BLA) for Deramiocel, the Company's investigational first-in-class cell therapy for the treatment of Duchenne muscular dystrophy (DMD).

As previously disclosed, the Company provided topline results from its Phase 3 HOPE-3 clinical study to the U.S. Food and Drug Administration (FDA) in late 2025. Following its review of these data, the FDA has formally requested the full HOPE-3 clinical study report (CSR) and supporting data to address the Complete Response Letter (CRL). The FDA did not request any additional clinical studies or new patient data as part of this request.

Preparation of the HOPE-3 CSR is well underway, and the Company plans to submit the requested materials to the FDA in February 2026. The Company expects that this submission will address the items outlined in the CRL and support continued review of the BLA, including the assignment of a new Prescription Drug User Fee Act (PDUFA) target action date.

"We are actively engaging with the FDA in order to facilitate an efficient review of the HOPE-3 data that directly address the issues raised in the CRL we received in July 2025. We were pleased that the FDA requested the HOPE-3 clinical study report, as this is an expected and appropriate next step following their initial review of the topline data," said Linda Marbán, Ph.D., Chief Executive Officer of Capricor. "The HOPE-3 results demonstrated statistically significant and clinically meaningful improvements in both skeletal muscle and cardiac function—key drivers of disease progression and long-term outcomes in Duchenne. These findings build on more than a decade of consistent clinical evidence and reinforce our confidence in Deramiocel's potential. Our near-term priority is to address the FDA's request and continue working collaboratively so that patients with late-stage DMD, who currently have very limited treatment options, may gain access to Deramiocel as soon as possible."

- **Capricor Therapeutics provided update following FDA review of HOPE-3 topline data which was submitted in late 2025.**
- **The company plans to submit the requested full HOPE-3 clinical study report (CSR) in February 2026.**
- **After Capricor's submission of the HOPE-3 CSR, it is expected that the FDA will restart the review clock with a new PDUFA target action date.**

Source : press release by Capricor Therapeutics on January 20, 2026

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I will now go on to explain the update on CAP-1002.

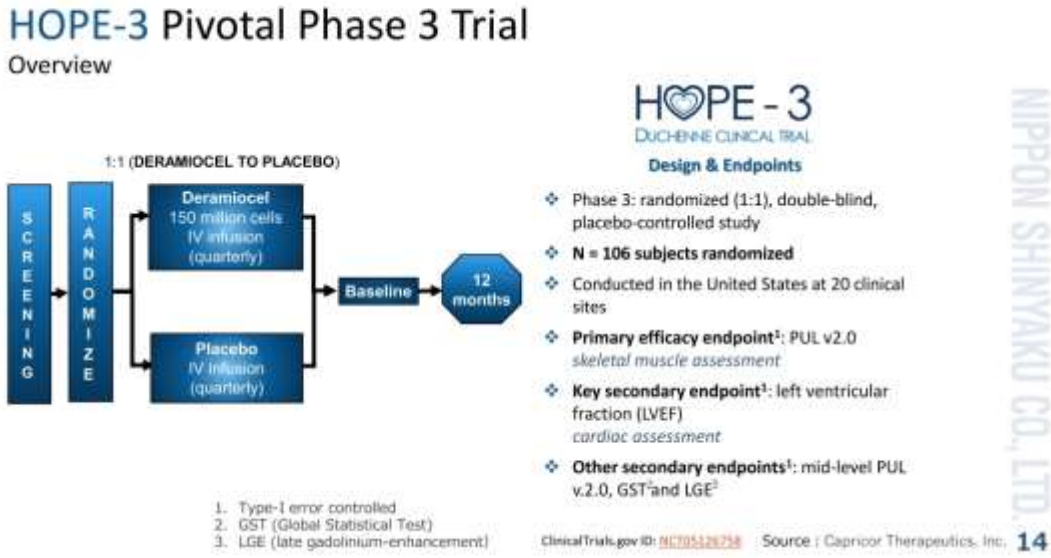
Please move on to slide 13.

I would like to explain CAP-1002, for which Capricor Therapeutics has filed a BLA, in accordance with the press release issued by Capricor.

After submitting topline data from the HOPE-3 to the US FDA late last year, Capricor plans to submit the HOPE-3 clinical study report this month as requested by the FDA. After the submission, it is expected that the FDA will restart the review.

CAP-1002 (deramiocel) HOPE-3 : Trial Design

- **HOPE-3 is a Phase 3, randomized, double-blind, placebo-controlled clinical trial.**
- **The primary efficacy endpoint is the mean change from baseline in upper limb function (PUL v2.0) and the key secondary endpoint is the cardiac MRI assessment at 12 months (LVEF).**



Please turn to slide 14.

Here is a brief introduction to the HOPE-3.

This is the trial design. The HOPE-3 is a randomized, double-blind, placebo-controlled study, to confirm efficacy at 12 months, and 106 patients were enrolled. The primary efficacy endpoint is PUL v2.0, which assesses upper limb function, and the key secondary endpoint is LVEF, the left ventricular ejection fraction.

CAP-1002 (deramiocel) HOPE-3 Topline Data : Baseline Demograhpics

- **In HOPE-3, all patients were 10 years of age or older, and approximately 85% of patients in both the placebo group and the Deramiocel group were non-ambulatory.**
- **Approximately 75% of patients had a diagnosis of cardiomyopathy.**

HOPE-3: Study Demographics

Baseline Demographics	Placebo (n=52)	Deramiocel (n=54)	Overall (n=106)[1]
Age (years)			
N	52	54	106
Mean (SD)	14.6 (2.95)	15.4 (3.10)	15.0 (3.04)
Median	14	15	15
Min, Max	10, 22	10, 22	10, 22
PUL v2.0 entry item score			
2,3	23 (44.2)	25 (46.3)	48 (45.3)
4,5,6	29 (55.8)	29 (53.7)	58 (54.7)
Diagnosed cardiomyopathy[2]			
No	14 (26.9)	13 (24.1)	27 (25.5)
Yes	38 (73.1)	41 (75.9)	79 (74.5)
Baseline LVEF%			
n	46	45	91
Mean (SD)	59.303 (6.108)	55.345 (7.743)	57.346 (7.206)
Median	59.309	55.892	57.532
Min, Max	47.395, 73.981	36.537, 71.112	36.537, 73.981
Ambulatory status			
Non-ambulatory	44 (84.6)	46 (85.2)	90 (84.9)
Ambulatory	8 (15.4)	8 (14.8)	16 (15.1)

[1]One subject enrolled but dropped out prior to baseline assessment (n=105)

[2]Updated as of Feb. 2026; subgroup: 64 of 79 patients with centrally reviewed and evaluable cardiac MRI LVEF assessments at baseline and 12 months

Source : Capricor Therapeutics, Inc. 15

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Please turn to slide 15. This is the baseline demographics of the HOPE-3.

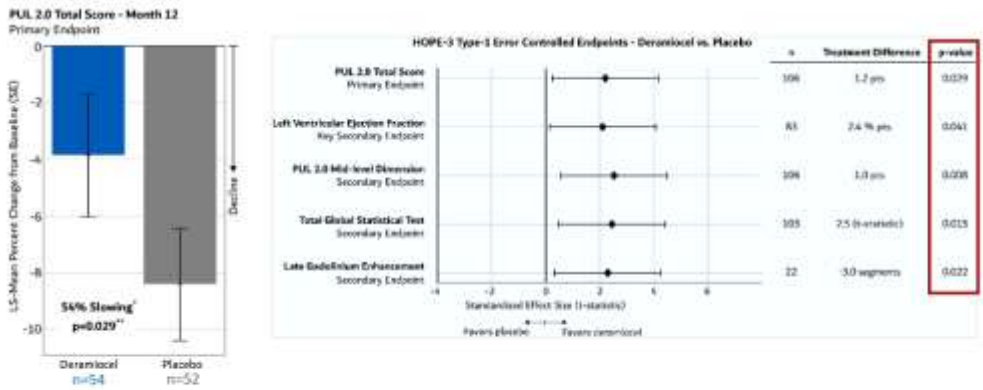
The HOPE-3 was targeted for patients 10 years of age and older, and the mean age of the enrolled patients in the trial was 15 years. Of the 106 patients, about 85% were non-ambulatory, and about 75% had cardiomyopathy.

CAP-1002 (deramiocel) HOPE-3 Topline Data : Efficacy

- **HOPE-3 study met the primary endpoint, performance of upper limb (PUL v2.0) and the key secondary cardiac endpoint, left ventricular ejection fraction (LVEF), both achieving statistical significance (p=0.029 and p=0.041, respectively)**

HOPE-3: Topline Efficacy Results

Primary Endpoint Met with Statistical Significance Achieved in **All** Type-1 Error Controlled Secondary Endpoints



*LS-Mean difference = 4.55 percentage point (1.2 -point difference on the PUL scale)
** Based on prespecified repeated measures model using percent change from baseline

Source : Capricor Therapeutics, Inc. 16

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Please turn to slide 16.

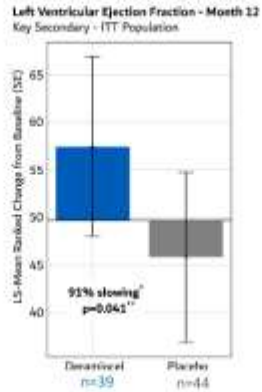
Here is a graph showing the results of the primary endpoint of the HOPE-3.

At 12 months from start of treatment, the rate of change from baseline in PUL v2.0 showed a 54% reduction in disease progression in the deramiocel group compared to the placebo group, a statistically significant delay in progression. Statistically significant results were also obtained for four secondary endpoints.

CAP-1002 (deramiocel) HOPE-3 Topline Data : Efficacy

HOPE-3: Topline Cardiac Efficacy Results

Left Ventricular Ejection Fraction



* LS-mean difference = 11.65 ranks (2.4 percentage point difference in LVEF)
** Based on prespecified rank ANCOVA model
LVEF: n reflects the number of patients in the ITT population with centrally reviewed and evaluable cardiac MRI LVEF assessments at baseline and 12 months (n=83)

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Source : Capricor Therapeutics, Inc. 17

Please turn to slide 17.

Here are the results of LVEF measured by cardiac MRI at 12 months after the start of treatment, the key secondary endpoint of the trial. The change from baseline in LVEF showed a 91% reduction in the cardiac function deterioration in the deramiocel group compared to the placebo group, a statistically significant delay in progression.

CAP-1002 (deramiocel) HOPE-3 Topline Data : Safety

- **Deramiocel maintained a favorable safety and tolerability profile consistent with results from previous clinical trials**

HOPE-3: Safety Profile Results

Overview	Placebo (n=52), n (%)	Deramiocel (n=53), n (%)	Overall (n=105[1]), n (%)
Any TEAEs	43 (82.7)	50 (94.3)	93 (88.6)
TEAEs related to IP or administration procedure	19 (36.5)	44 (83.0)	63 (60.0)
TEAEs related to IP	16 (30.8)	44 (83.0)	60 (57.1)
TEAEs related to administration procedure	9 (17.3)	23 (43.4)	32 (30.5)
TEAEs related to IP or administration procedure by maximum severity			
Mild (grade 1)	15 (28.8)	19 (35.8)	34 (32.4)
Moderate (grade 2)	3 (5.8)	25 (47.2)	28 (26.7)
Severe (grade 3)	0	0	0
Life-threatening (grade 4)	1 (1.9)	0	1 (1.0)
Fatal (grade 5)	0	0	0
TEAEs leading to death	0	0	0
Any serious TEAEs	5 (9.6)	1 (1.9)	6 (5.7)
Serious TEAEs related to IP or administration procedure	1 (1.9)	1 (1.9)	2 (1.9)

[1] Safety population (n=105)

Source : Capricor Therapeutics, Inc.

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Please move on to slide 18.

These are the safety results, which show that the drug maintains a favorable safety and tolerability profile consistent with results from previous clinical studies. Capricor plans to submit the clinical study report for the HOPE-3 that I have just introduced to you to the FDA in the near future, which we expect will restart the FDA's review.

RGX-121 (clemidsogene lanparvovec) Update

NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

January 29, 2026

Regulatory Update on RGX-111 and RGX-121

KYOTO, Japan, January 29, 2026 - Nippon Shinyaku Co., Ltd. (Headquarters: Kyoto, Japan, President: Toru Nakai) announced that REGENXBIO Inc. (REGENXBIO; Headquarters: Rockville, Maryland, USA; CEO: Curran M. Simpson, NASDAQ: RGNX) has received a notification that the U.S. Food and Drug Administration (FDA) placed a clinical hold on RGX-111 and RGX-121.

For more details, please see the press release from REGENXBIO.
https://ir.regenxbio.com/news-releases/news-release-details/regenxbio-announces-regulatory-update-ultra-rare-mps-programs

RGX-111 and RGX-121 are gene therapies being developed by REGENXBIO for the treatment of mucopolysaccharidosis type I (MPS I, Hurler syndrome) and mucopolysaccharidosis type II (MPS II, Hunter syndrome), respectively. The FDA has accepted the Biologics License Application (BLA) filing for RGX-121 in May 2025.

In January 2025, Nippon Shinyaku and REGENXBIO have entered into a strategic partnership for RGX-111 and RGX-121, under which Nippon Shinyaku acquired exclusive commercialization rights in the U.S. and exclusive development and commercialization rights in Asia including Japan. After REGENXBIO obtains BLA approval for each product in the U.S., NS Pharma, Inc. (New Jersey, USA, President: Yukiteru Sugiyama), a wholly owned subsidiary of Nippon Shinyaku, will market them in the U.S.

Source : January 29, 2026 Company press release

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I will now go on to explain the update of RGX-121.

Please move on to slide 20.

Our partner REGENXBIO received a clinical hold from the US FDA for RGX-111 and RGX-121 for the treatment of mucopolysaccharidosis. This was due to a single case of neoplasm in a participant treated in the Phase I/II study on RGX-111. The decision to place RGX-121 on clinical hold was based on similarities in product characteristics, patients studied, and risks in the clinical trial, to RGX-111.

At this time, REGENXBIO have not yet received official documentation and are awaiting additional information. We will continue to prepare for sales expansion of its products in the US.

That is all from me.

Next, Mr. Kuwano in charge of R&D will explain the R&D pipeline.

R&D Updates (1/2)

For updates from Q2 FY2025 financial results announcement on November 14, 2025, see highlighted text in red.

Update	Code No. (Generic name)	Brand name	Indications and topics	Schedule
P3	NS-065/NCNP-01 (viltolarsen)	Viltepso	· CSR for Study 301 under the FDA's review · Inquiring with FDA regarding the protocol for Study 303	January 2026
Approved	NS-401 (tagraxofusp)	Elzonris	blastic plasmacytoid dendritic cell neoplasm (BPDCN)	December 2025
Additional indication	ACT-064992 (macitentan)	Opsumit	Johnson & Johnson obtained approval for the treatment of pediatric patients with pulmonary arterial hypertension (PAH) in Japan	December 2025
Additional indication	LY3527727 (pirtobrutinib)	Jaypirca	for patients with relapsed or refractory chronic lymphocytic leukemia (including small lymphocytic lymphoma) who are resistant or intolerant to other BTK inhibitors	September 2025
Launch	NS-304 (selexipag)	Uptravi	Uptravi Tablets for Pediatric 0.05 mg	March 2025
Filed	RGX-121 (clemidsogene lanparvovec)	–	Mucopolysaccharidosis Type II (the FDA placed a clinical hold)	January 2026 (U.S.)
Filed	CAP-1002 (deramiocel)	–	Duchenne muscular dystrophy cardiomyopathy (Capricor Therapeutics announced positive topline results from Pivotal Phase Ⅲ HOPE-3 Study)	December 2025 (U.S.)
Revision of electronic package insert	GA101 (obinutuzumab)	Gazyva	Combination therapy with venetoclax has become available for previously untreated chronic lymphocytic leukemia	November 2025
P3			Roche announced Global Phase Ⅲ INShore Study topline results for Idiopathic nephrotic syndrome in children and young adults	October 2025
P3	ZX008 (fenfluramine hydrochloride)	–	UCB announced that P3 for CDKL5 deficiency disorder (CDD) indication met primary and most key secondary clinical endpoints	June 2025
Start of P1	NS-245	–	Treatment for inflammatory diseases	December 2025

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Kuwano: I am Kuwano in charge of research & development. I will continue with the R&D pipeline that has been updated since the financial results of Q2 of FY2025.

Please turn to slide 22.

With regard to Viltepso, we have received confirmation that the FDA's review of the Study 301 report is ongoing. In addition, we continue to make inquiries to the FDA regarding the final protocol for Study 303.

NS-401 Elzonris received manufacturing and marketing approval from the Ministry of Health, Labor and Welfare in December last year.

As for Opsumit, in December last year, Johnson & Johnson received approval for an additional indication for pulmonary arterial hypertension in pediatric patients. They have also obtained manufacturing and marketing approval for dispersible tablets for pediatric use.

Regarding RGX-121, we received a clinical hold from the FDA in January for the clinical trial and are awaiting additional information from the official document.

As for CAP-1002, the HOPE-3 topline data was obtained in December last year, and now Capricor plans to submit the HOPE-3 clinical study report this month as requested by the FDA.

With regard to Gazyva, the combination therapy with venetoclax, a molecular targeting agent that inhibits BCL-2, has been available for previously untreated chronic lymphocytic leukemia since November last year.

As for NS-245, in December last year, we started the Phase I study for inflammatory diseases.

R&D Updates (2/2)

For updates from Q2 FY2025 financial results announcement on November 14, 2025, see highlighted text in red.

Update	Code No. (Generic name)	Brand name	Indications and topics	Schedule
Collaboration	–	–	Launch of co-creation project to evaluate drug discovery seeds with FRONTEO, Inc.	December 2025
Research Alliance (Boston Children's Hospital)	–	–	a strategic alliance with the aim of developing and delivering innovative therapies for rare diseases	July 2025 (U.S.)
Fast Track Designation	NS-229	–	eosinophilic granulomatosis with polyangiitis (EGPA)	September 2025 (U.S.)
Orphan Drug Designation				April 2025 (U.S.)
Orphan Drug Designation	NS-051/NCNP-04	–	Duchenne muscular dystrophy	September 2025 (U.S.)
Academic conference presentation	NS-089/NCNP-02 (brogidirsen)		3.5-Year clinical trial data presentation at the World Muscle Society 2025 Congress	October 2025

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Please move on to slide 23.

As part of open innovation in drug discovery seeds for intractable and rare diseases, we launched a co-creation project utilizing AI technology with FRONTEO in December last year.

That is all for the R&D pipeline.

Elzonris® : Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)

- **Blastic plasmacytoid dendritic cell neoplasm (BPDCN) is a rare hematopoietic tumor with a poor prognosis that originates from plasmacytoid dendritic cells (pDC)**
- **The median age at diagnosis is around 70 years, and the number of patients is extremely small.**
- **Currently, there are no drugs indicated for BPDCN in Japan, nor is there a Standard of Care for the disease. The median survival time with existing therapies is 7-13 months, which is a poor prognosis, and the number of patients who can be treated with intensive chemotherapy is limited. Therefore, new treatment options are needed.**

Product Overview	
Development code number	NS-401
Generic name	tagraxofusp (genetical recombination)
Product name	Elzonris® 1000μg for intravenous infusion
Manufacturing and marketing approval	December 22, 2025
Indications	Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
Origin	The Menarini Group (Italy) Elzonris has been approved in over 40 countries. In March 2021, Nippon Shinyaku acquired the rights in Japan.

SHINYAKU CO., LTD.

Then, I will introduce the R&D topics.

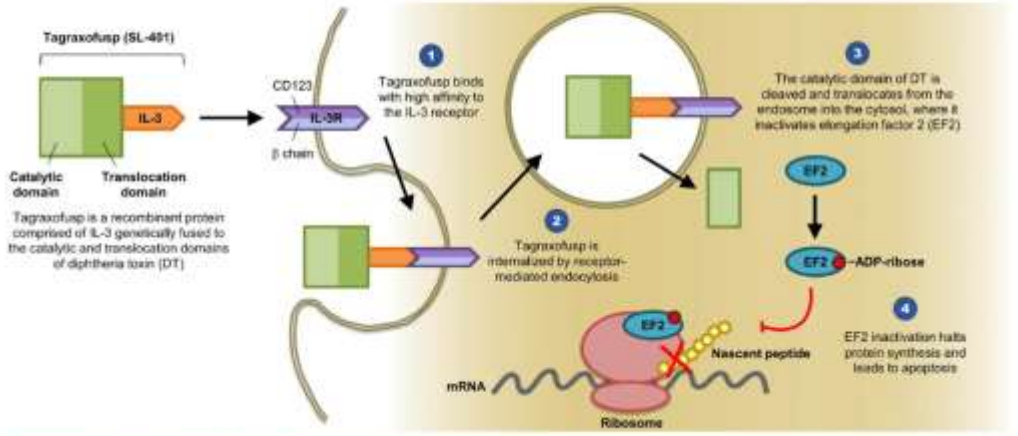
Please turn to slide 24.

First of all, I would like to introduce Elzonris, a therapeutic agent for BPDCN, for which we obtained manufacturing and marketing approval last December.

BPDCN is a rare hematopoietic tumor with a poor prognosis that originates from plasmacytoid dendritic cells. The median age at diagnosis is around 70 years, and the number of patients in Japan is extremely small, making it a rare disease. Currently, there are no drugs indicated for BPDCN in Japan, and the disease has a poor prognosis with a median survival of 7 to 13 months, so new treatment options are needed.

Pharmacological Action of Elzonris®

- **The first drug targeting CD123**
- **While minimizing toxicity to normal tissues, Elzonris exhibits selective cytotoxic activity against BPDCN cells expressing CD123 (IL-3Rα).**



Clinical Activity and Tolerability of SL-401 (Tagraxofusp): Recombinant Diphtheria Toxin and Interleukin-3 in Hematologic Malignancies - PubMed

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Please turn to slide 25. Here is a diagram showing the pharmacological action of Elzonris.

It is the first therapeutic agent that targets a cell surface protein called CD123. It specifically binds to CD123 overexpressed on BPDCN cells, inhibiting protein synthesis and inducing apoptosis, which results in the death of BPDCN cells.

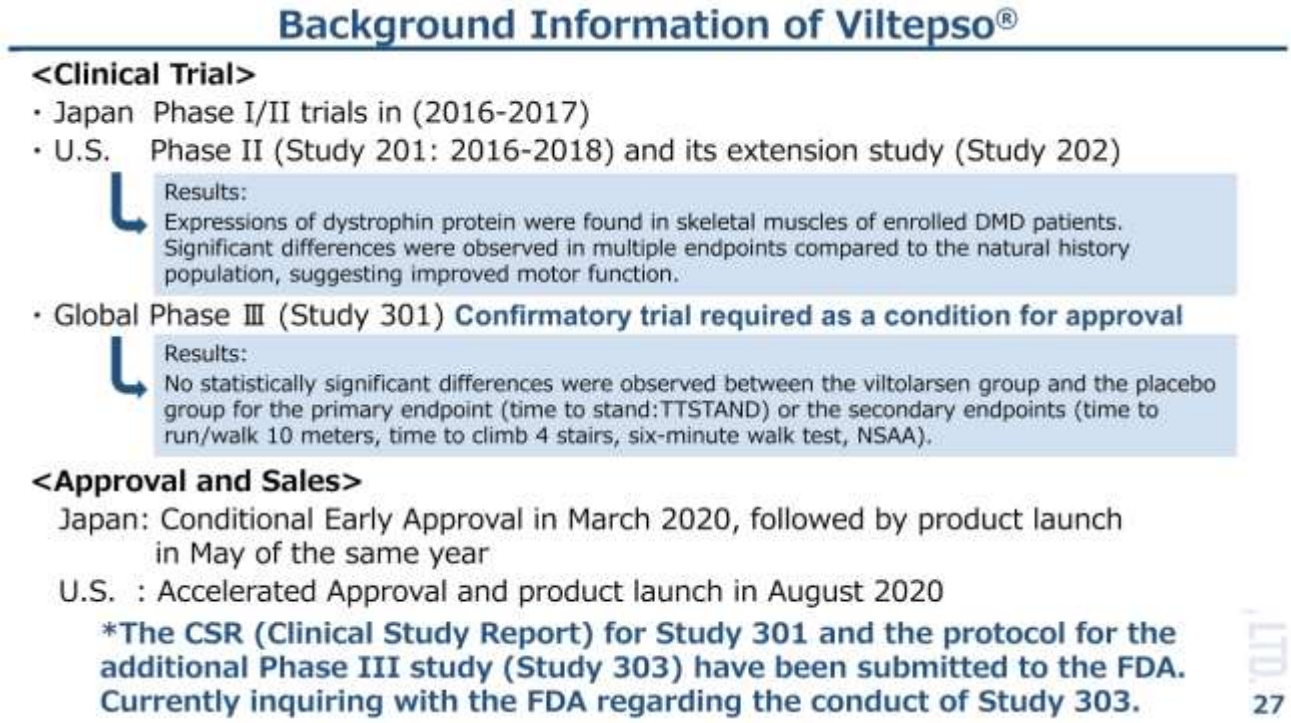
Based on the results of the Phase I/II studies conducted overseas for untreated and relapsed/refractory BPDCN patients, the drug was approved for the indication of BPDCN in the US in December 2018 and untreated BPDCN in Europe in January 2021, and has already been approved in more than 40 countries.

The drug was in-licensed from the Menarini Group in March 2021 and was under development.

The manufacturing and marketing approval is based on the results of the Phase I/II studies conducted by our company for BPDCN patients in Japan and an overseas Phase I/II studies conducted by Stemline Therapeutics, a Menarini Group company.

We believe that we can contribute to the treatment of BPDCN by appropriately delivering this drug to patients who need it.

Next, I would like to reiterate the outline of Study 303 on Viltepso that we are currently inquiring with the FDA.



Please move on to slide 27.

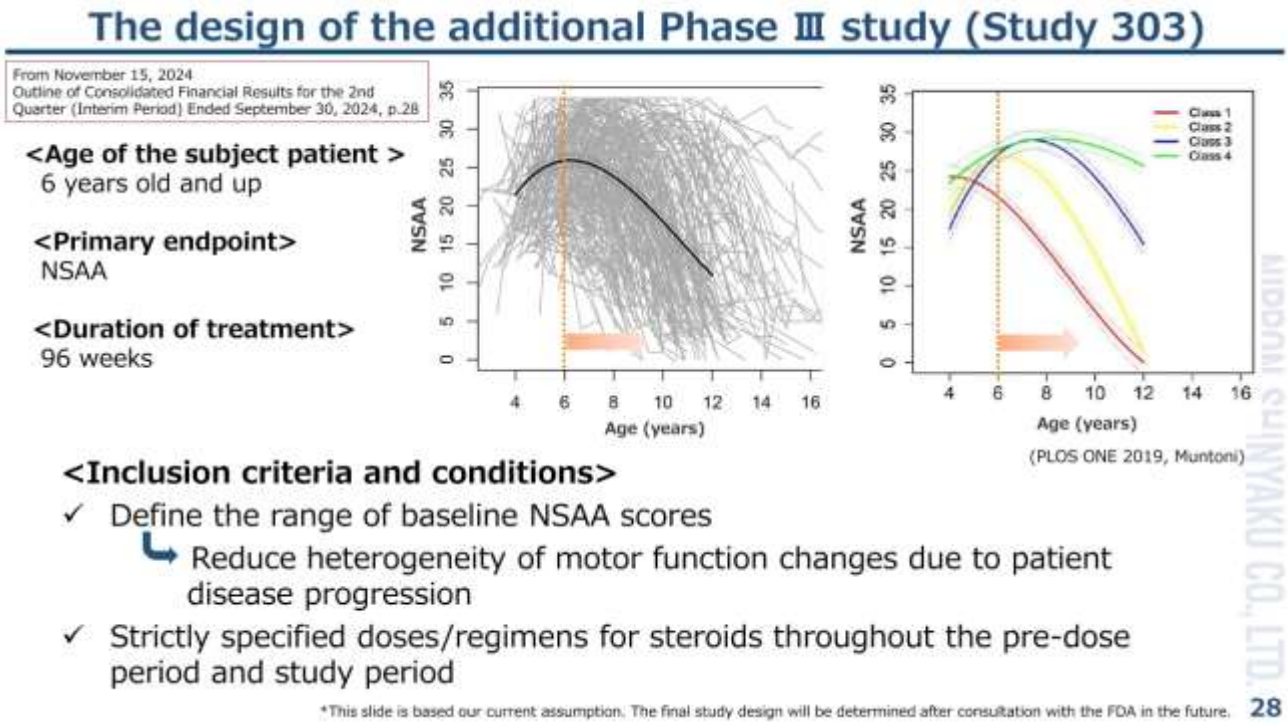
First, I would like to provide a brief summary of the background to date.

In the Phase I/II trials in Japan and Phase II trial in the US, Viltepso has been shown to express dystrophin protein in the skeletal muscles of DMD patients, suggesting improved motor function compared to natural history.

With these results, we received conditional early approval in Japan in March 2020 and accelerated approval in the US in August 2020. The product was launched in Japan in May 2020 and in the US in August 2020, and has been used by many patients in clinical settings.

In May 2024, we announced the results of Study 301, a global Phase III confirmatory trial required as a condition for approval, which showed no statistically significant difference in the primary endpoint of "time to stand" compared to the placebo group.

Based on the results, we are currently inquiring with the FDA about conducting an additional Phase III study, Study 303, while continuing to market Viltepso. I will explain our planned protocol on the next slide.



Please turn to slide 28.

Based on the results of Study 301, we are proposing a study design that will confirm the efficacy and safety of Viltepso for an additional Phase III study, Study 303, with inclusion criteria such as patient age of at least six years, dosing period of 96 weeks, and strict stipulations regarding steroid administration.

Please note that the information on this design is prior to agreement with the FDA.

New information regarding Viltepso will be disclosed as soon as the situation changes.

That is all for the R&D pipeline and topics.

Question & Answer

Takechi [M]: Then, we will now go to the question-and-answer session.

We will take questions first from analysts and institutional investors, and then move on to questions from members of the press. If you have any questions, please click the raise hand button. When asking questions, please state the name of the company and your name before speaking.

Now, we will take your questions. Mr. Yamaguchi from Citigroup Global Markets, please ask your questions.

Yamaguchi [Q]: I am Yamaguchi from Citigroup Global Markets. Thank you for taking my question.

First, I understand the results up to Q3 and the current changes in sales. You have also announced an addition of JPY500 million in SG&A expenses and another JPY2 billion in R&D expenses. The increase of R&D expenses is particularly large for nucleic acid. Is this increase due to certain circumstances? I would like to know about these two if there is any circumstance, or is this increase due to the situation where they might not be used up?

Nakai [A]: Thank you for your question. We have increased R&D expenses by JPY2 billion compared to the previous forecast, but we are actually moving toward with clinical trials not only for nucleic acid products but also for other R&D pipelines, so these expenses have been added to the previous forecast. Mr. Edamitsu, if you have anything to add. Is this okay? That is all.

Yamaguchi [Q]: I understand. So, will this level be the base for the next fiscal year as well? It seems to be about JPY37 billion, or a little increase from there for next fiscal year?

Nakai [M]: Edamitsu will comment on that.

Edamitsu [A]: For the next fiscal year, of course, the figures for the current fiscal year will be used as a base, but the contract research expenses and manufacturing costs for nucleic acid investigational products will not necessarily be at the same level as the previous fiscal year. So, we will inform you of the figures for the next fiscal year on a later date.

Yamaguchi [Q]: Thank you. Also, I have appreciated your explanation on Viltepso. Originally, you were anticipating their reply to come, maybe a little earlier or last year. I think it's a story with a partner, so you are still waiting. If there is a reason for the delay, I would appreciate it if you could tell me, and if not, or if you are really just waiting, I would appreciate it if you could tell me when the reply is going to come, even though you may not know.

Kuwano [A]: Thank you for your question. I will answer your question. We had hoped to hear back from the FDA by the end of December, as you mentioned, but that has not happened. We have inquired about this and have been told that it will take a little more time to review and the timing for the reply is unclear at this time. That is all.

Yamaguchi [Q]: That is unclear at this time.

Kuwano [A]: Yes.

Yamaguchi [Q]: I understand. Thank you. Lastly, it is very helpful that your company provides various information according to the information released by Capricor. That is very much appreciated. The clinical

study report will be submitted soon in February, and after submission, the PDUFA will be set, so the result may be obtained in August. Is that understanding correct?

Nakai [A]: Thank you for your question. What you just mentioned is fine. They will submit the CSR in February, and then the FDA will probably contact them with confirmation of acceptance plus PDUFA, and there will be a 6-month review period, so the scheduled approval date will be around August or September.

Yamaguchi [M]: Thank you. That is all.

Takechi [M] : Next, Mr. Wakao from J.P. Morgan Securities, please ask your question.

Wakao [Q]: I am Wakao from J.P. Morgan. Thank you for taking my question.

First, I would like to ask about CAP-1002, deramiocel. I think the PDUFA date will be notified, and I think it will be around August. What I would like to know is, when do you expect the timing of the market launch to be for your preparations now? I believe that you were expecting approval in the summer of the current fiscal year and preparing for the market launch that is scheduled for January to March. What is the current schedule? Since some preparations are underway, I think it would be possible to put it on the market immediately after it is approved in the summer.

Nakai [A]: Thank you for your question. After actually obtaining approval, we believe it will take several months to physically prepare the products. For example, when it is approved, an approval number is assigned, and it takes time to attach the number to the package and perform other practical tasks. We have also experienced a slight time lag between approval and actual insurance reimbursement in the case of Viltepso and other products, so we expect that it will take several months as preparation period to actually launch the product after approval is obtained.

Wakao [Q]: So, if the product is approved in August, should I think in terms of a time frame, you can start selling it just before the end of the year?

Nakao [A]: Yes. I think it is safe to assume that.

Wakao [Q]: On the other hand, should I understand that the costs for the launch have already been incurred? Or from the beginning of the next fiscal year?

Nakai [A]: We have already spent some money on the development of the launch system, and those costs will continue to be incurred in the next fiscal year. We also expect to incur additional costs such as one-time consulting fees and other unexpected expenses in the next fiscal year.

Wakao [Q]: I understand. Am I correct in understanding that this would result in more expenses for the next fiscal year, and also that the approval milestone would be recorded on your P&L when it is approved?

Nakai [A]: Thank you. The idea is to capitalize the asset first and then depreciate it.

Wakao [Q]: I understand. Another question is what kind of approval you can get from the data you are getting. I am a little concerned that HOPE-2 and HOPE-3 are for a rather older age group, so should I assume that the approval is for such older patients?

The tone of the discussion so far seems to have been that there are no such restrictions. Looking at the HOPE-2 and HOPE-3 data again, I see that they are mainly for non-ambulatory children who are relatively old, so I am not sure if children who can walk are also eligible. Please tell me this point.

Nakai [A]: Thank you. First, I am sure you are aware that we cannot say anything definite about the indication yet, as it will be decided as a result of discussions with the FDA. For example, in Viltepso, the approval was obtained using data from four to seven years of age, but it can be used for patients subject to exon 53 skipping regardless of age.

From that point of view, we believe that there is a possibility that the age of the patients will not be particularly considered in the case of CAP-1002 as well, where patients aged 10 and over have been enrolled. This is really up to a discussion with the authorities.

Even if it is bound to be non-ambulatory patients, half of all DMD patients are non-ambulatory. In this HOPE-3, 85% of the patients are non-ambulatory, and if the target is limited to non-ambulatory patients based on this concept, as I mentioned earlier, we assume that half of the DMD patients will be covered.

Wakao [Q]: I understand. Lastly, please let me know about RGX-121. I think the reason it has stopped is more of 111 than 121. What is the outlook for the future?

You said earlier that your company will continue to do its best, but if it takes a long time, I think you should consider the costs involved, or even suspending the agreement, although you have already licensed in this. What do you think?

Nakai [A]: Thank you. In fact, as for the clinical hold that REGENXBIO received this time, we have not yet received a written statement of the details of the hold, so I hope you understand that we are not in a position to comment on how we can do so at this time.

We will have to make a decision on our future approach to this product after carefully examining the documents once we know the details of the clinical hold. I hope you will forgive me for this now.

Wakao [Q]: I understand. I guess you can't say for sure since you don't know yet, but in the meantime, is there a possibility of quitting if it seems to take a long time? If CAP-1002 and other products work well, I don't think you need to cling to this. What do you think?

Nakai [A]: I understand your point, of course, but we would like to consider the positioning and priority of this product in the overall scheme while examining the whole picture.

Wakao [M]: I understand. Thank you. This is all.

Takechi [M]: Now, Mr. Tanaka from Mizuho Securities, please ask your question.

Tanaka [Q]: I am Tanaka from Mizuho Securities. Thank you.

As for RGX-121, I understand the FDA's concern because the vectors are the same. On the other hand, the dosage is quite small, so I thought it would be safe because it is administered locally, but it was not. What kind of things in the future does your company think will allow this clinical hold to be lifted? Are you already leaving everything to REGENXBIO?

Kuwano [A]: Thank you for your question. Since we do not actually have the data, it is difficult to say what exactly we should do about it. We look forward to further action by REGENXBIO. That is all.

Tanaka [Q]: Quite a few of those REGENXBIO vectors are used in other gene therapies.

Kuwano [A]: Yes.

Tanaka [Q]: Well, so I guess it came as a surprise. Second, it has taken more than a year for Viltepso but it hasn't moved at all, so I am wondering what is taking so long from your company's point of view. Of course it has been said that the FDA has been restructured and is not making much progress. Is there any new information on what is taking so long from your company's point of view?

Kuwano [A]: As I mentioned earlier, we were expecting a reply by the end of last year, but surprisingly, we have not received any reply at all. Then, we inquired with the FDA and they said that it would take more time.

That is their reply, so we can only imagine the rest. I think Sarepta, for example, would be in a similar situation. So, we can only imagine that they are thinking comprehensively about how to respond to these items and medicines. That is all.

Tanaka [Q]: I understand. Thank you. Lastly, the cost ratio is worse this fiscal year, and this is due in large part to the change in Erleada's contract, isn't it?

Edamitsu [A]: Thank you for your question. Of course, the cost ratio has been affected by that factor, as well as other factors such as the impact of the NHI price revision, as noted in the materials. That is all.

Tanaka [Q]: The way you spend your money hasn't really changed as a result of the reverse co-promotion, has it? Your company's sales are increasing and the expenses are used from each other's SG&A or selling expenses, right? It means that the share remains the same, doesn't it?

Nakai [A]: Thank you. As you have pointed out, since the product was formerly categorized as a co-promotion category within our company, Erleada has rather a high cost ratio. The scheme is not so different from the previous partnerships where sales are generated and cost of sales is subtracted, while resources for sales activities are used as SG&A expenses. The remaining amount is posted as a profit.

Tanaka [Q]: I'm not sure why you did this reverse co-promotion in the first place. Is it because you wanted to record it as your company's sales? If the profit doesn't change, I don't see much point in doing it.

Nakai [A]: Thank you. One reason for this contract change is that the contract term has been extended. Previously, the contract was for a period through 2027. That timing is the same as the timing of the Uptravi patent expiration, leading to the loss of co-promotion revenue, and I would like you to understand that we have positioned Erleada as a product that will continue to contribute to our profits after that time.

Tanaka [M]: I understand. Thank you.

Takechi [M]: Now, Mr. Yamakita from Jefferies, please ask your questions.

Yamakita [Q]: I am Yamakita from Jefferies. Thank you.

I would also like to ask about the costs, first. In the next fiscal year, R&D expenses will probably increase, and the year after next, royalties will decrease due to the expiration of the Uptravi patent. I also think that it's time for a European option for CAP-1002.

I hope the initial sales after launch of CAP-1002 goes well, but I think it is a risk to increase costs too much. I am wondering if you will focus on the areas where you have to spend and control costs in other areas, or if you think it a period when costs will increase. Could you tell me a little more about your thinking on costs?

Edamitsu [A]: Thank you for your question. I will answer that question. At the time of the announcement at the beginning of the current fiscal year in May, we had planned to launch the CAP-1002 in the current fiscal year.

That was revised in August. If you remember the figures at that time, you can see this, but as you pointed out, we are trying to control expenses so that we do not incur costs ahead of time. In the next fiscal year, we will start from scratch again, but we will take this into consideration when constructing the figures. That is all.

Yamakita [Q]: Thank you. I think there will be a considerable increase in SG&A expenses, and do you have any thoughts on whether to control it in SG&A expenses or whether to control it as an overall cost, including R&D, as an operating cost?

Edamitsu [A]: Of course, the CAP-1002 itself is part of the SG&A expenses, but of course we would like to control the overall costs, including R&D expenses. That is all.

Yamakita [Q]: Thank you. Second, considering mainly the period of your company's medium-term management plan, I think the situation is quite dependent on the success of CAP-1002 to achieve the plan. I think the situation is changing now that RGX-121 is under a clinical hold. For example, do you plan to introduce a pipeline that is a little larger than the RGX-121, if not that large as the second CAP-1002? Please let me know about your business investments.

Nakai [A]: Thank you for your question. As for plans for future introduction, the BD team is currently working on a product of the same size as the RGX-121, or even larger, with potential, and we are in the process of having the team promote the possibility of concluding a contract. This is also within the scope of our medium-term strategic and growth investments, and we are currently working on licensing activities for growth.

Yamakita [M]: Thank you. That is all from me.

Takechi [M]: Now, Mr. Wada from SMBC Nikko Securities, please ask your questions.

Wada [Q]: I am Wada from SMBC Nikko Securities. Thank you. I would like to ask about the two data set from the HOPE-3 trial compare to the HOPE-2 data.

I would like to ask you about LVEF because that is easier to understand. If we look at the ranked change described in small letters at the bottom, that seems to be much smaller than HOPE-2. In HOPE-2, the ranked change is 45.7, in HOPE-3 it is 11.65, and the percentage point difference is 2.4, compared to 4 in HOPE-2. I would like to know if this difference will affect the approvability?

Kuwano [A]: I will answer that question. I cannot say whether the difference affects the approval or not. I'm sorry. This is all.

Wada [Q]: In terms of the value, maybe the deramiocel data is not that different, but the placebo data is much smaller. In HOPE-2, the LVEF is around 8, but this time it seems to be much smaller. Does the value become smaller because the number of subjects has increased?

Kuwano [M]: Sorry. Does the secretariat have any views on this?

Beppu [A]: I am Beppu from R&D Planning and Administration Division. Regarding your question, in the HOPE-2, there were much fewer cases in both active and placebo groups. We cannot give a definitive answer as to where this difference comes from, but we believe that it may be due to the difference in the number of subjects.

Wada [M]: I understand. Thank you. That is all.

Takechi [M]: Mr. Lee from Morgan Stanley MUFG Securities, please ask your question.

Lee [Q]: I am Lee from Morgan Stanley. I have two questions.

In terms of individual products, I believe you have made a downward revision on a dollar basis for Viltepso. At the time of the Q2 results, you said that new patients were trending upward. I think you made the comment that you can aim for re-growth. In the end, am I correct in assuming that sales would remain flat from the next fiscal year onward due to the impact of the insurance and this kind of decrease in dosage?

Nakai [A]: Thank you for your question. As you can see in the comment in the US section on slide seven that you are currently looking at, the growth in the number of patients eventually reached a plateau, because although the number of newly acquired and administered patients increased, some patients dropped out because their insurance was not reimbursed, and thus the total number of patients remains unchanged. Although there has been an increase in real terms, the trend has been flat.

The age of the increased, or newly administered patients, is getting younger, as you can see in this second checkmark. The composition of the patient population is changing, with new, very young patients coming in, as older patients' conditions are deteriorating and they are dropping out due to the sticker insurance reauthorization.

Therefore, we must understand that the overall growth will not be achieved unless we acquire more patients than we had originally planned. On the other hand, the fact that we have more younger patients means that they continuously use the drug. Therefore, in total, the sales of Viltepso have been flat recently, but if new patients continue to receive the drug, we can expect growth of Viltepso.

Lee [Q]: Thank you. So do you believe that your company will be able to continue its growth trend in the next fiscal year and beyond?

Nakai [A]: Yes. We aim to see such situation.

Lee [Q]: Thank you. Second, as for the overall results, this overlaps with Mr. Yamaguchi's question, but the progress rate of operating profit looks pretty good. On the other hand, I think the full-year plan has been left unchanged in view of the increase in R&D and other factors. If we take into account the royalty income from Uptravi and other income such foreign exchange gains, there seems to be a little upside. What do you think about that?

Nakai [A]: By passing through Q4 on a strong note, we will aim to generate a result that exceeds our revised forecast at the end of the fiscal year. As I said, we have added JPY2 billion to our R&D expenses this time, and I would like to reiterate that R&D will be required at higher stages of development, not just for nucleic acid medicine. I would like you to understand that our stance is to make more aggressive R&D investments for future growth and these figures reflect our stance of investing more aggressively in R&D for future growth.

Lee [Q]: Thank you. This is a follow-up to this R&D expenses. This time, the amount was revised upward by JPY2 billion. In Q2, R&D was reduced by JPY4.5 billion from JPY39.5 billion at the beginning of the fiscal year to JPY35 billion. Is it correct in understanding that the increased amount of JPY2 billion is for new projects? Or is something that had been planned to occur next year brought in this fiscal year? Please follow up on this point.

Edamitsu [A]: Thank you for your question. I will answer that question. As you mentioned, the R&D expenses that were scheduled to be incurred this fiscal year have been moved to the next fiscal year, and the expenses for other new items have also increased.

Therefore, in that regard, I think it is fair to say that some costs for the next fiscal year are being brought in this fiscal year. That is all.

Lee [M]: I understand very well. Thank you. That is all from me.

Takechi [M]: How about other analysts and institutional investors? We will now take questions from the press. Mr. Adachi from Nikkei, please ask your question.

Adachi [Q]: I am Adachi from Nikkei. I would like to ask President Nakai.

I think there has been a movement all along that the Trump administration in the US is demanding a reduction in drug prices. I would like to ask about the feasibility of this, or rather, whether it will really happen, and the impact on your company, especially in the next fiscal year, or whether the impact will appear or not.

Nakai [A]: Thank you for your question. I understood your question to be about how various policies of the Trump administration, such as MFN drug pricing, would affect our products.

I understand that the US government has now reached an agreement with the so-called mega-pharmaceutical companies, or just less than 20 mega-pharmaceutical companies, on how they will respond to MFN drug pricing.

We have Viltepso, and this is a drug that is currently on the market in the US and Japan, so I am sure you understand that we are not in a situation where we are directly asked to lower the US price, based on the concept of MFN drug pricing.

As for Uptravi Johnson & Johnson is responsible for overseas sales, I understand that there were reports this past January that Johnson & Johnson had reached an agreement with the US government on the pricing. We are currently examining the details and the impact on Uptravi, but there may be some impact on Uptravi.

In addition, with regard to the products that we will develop and market in the future, we are currently examining the countries where we will launch our products, taking into consideration the price policies of the Trump administration. That is all.

Adachi [Q]: Thank you. Now, regarding your last comment, could you please elaborate a bit more on the part about taking into account the countries that you are going to be on the market, and how they will be taken into account?

Nakai [A]: Thank you. For example, among regions and countries that are subject to MFN, for example, there are European countries when considered from the perspective of OECD member countries. Therefore, when we make a decision to enter the European market, we need to consider whether to prioritize our business in the US over Europe.

Adachi [M]: I understand. Thank you.

Takechi [M] : Now, Mr. Kuriyama from Yakuji Nippo, please ask your questions.

Kuriyama [Q]: I am Kuriyama from Yakuji Nippo.

You have mentioned the background of the slight decrease in sales of Viltepso in the US. I would like to ask you a little more about the overall market as a whole. Could you talk about the current status of the DMD drug market in the US, trends in competing drugs, and the positioning of Viltepso in this market, as well as how it will evolve in the future, from an overall perspective?

Nakai [A]: Thank you for your question. We have received very positive feedback from physicians and patients who have actually used Viltepso.

However, as mentioned earlier in the question-and-answer session, the reauthorization process for insurance coverage is becoming slightly stricter. It has already been five years since Viltepso was launched, and 2026 will mark its sixth year.

Although some patients who have actually been treated with Viltepso have experienced a slow progression of their disease, some patients have become unable to walk due to worsening of their disease. The situation has come to a point where these patients are no longer being covered by insurance.

Insurance companies use this as a basis for making judgments, and since there are other drugs and treatments that have been approved, they have been advised to be treated with such drugs and the competitive environment is becoming more and more intense.

In this context, we would like to maximize the value of this product by fully introducing to medical institutions the efficacy and, above all, the safety of Viltepso.

Kuriyama [M]: Thank you. This is all.

Takechi [M]: Now, Mr. Okada from Yakuji Nippo, please ask your questions.

Okada [Q]: Thank you. I am Okada from Yakuji Nippo. Regarding Elzonris, you mention that the number of patients is extremely small, but how many patients are there, and do you have any numerical indicators for future sales, such as a rough estimate?

Iwata [A]: I will answer that question. The number of cases is expected to be extremely small, roughly 40 cases per year. As for sales, we are not able to say anything about sales since the NHI price has not yet been set. That is all.

Okada [M]: I understand. Thank you.

Takechi [M]: Do you have any other questions? Mr. Wakao from J.P. Morgan Securities, please.

Wakao [Q]: Excuse me, please let me know one point. Is there any change regarding the current US government policy on patient access to exon skipping drugs?

There was posting in mid-December that the patient met with RFK (Mr. Robert F. Kennedy, Jr., the Secretary of US Department of Health and Human Services) and asked him not to change the access to the skipping medication and RFK said he would not change it. At our J.P. Morgan Healthcare Conference, there was also a discussion about this during the question-and-answer session for Sarepta Theapeurics.

I'm not sure if they really met or not, or what RFK said or didn't say, but the tone seemed to be that even though the Phase III trial is not going well for them and not going well for you, it didn't seem like there would be a sudden breakdown in patient access. I think the tone of the discussion was something like that. I would like to know if there is anything you are aware of, or if there is anything you can tell us about your company's current views.

Nakai [A]: Thank you. We have confirmed such an exchange during the question-and-answer session for Sarepta Therapeutics' presentation at the J.P. Morgan Healthcare Conference.

We have also confirmed that the posting contained information not only about Sarepta's product but also about our company's Viltepso. However, there is no direct communication between the patient and NS Pharma nor is there any direct dialogue with RFK through that patient.

The US policy seems to be to protect patient access to drugs for diseases with no other treatment options, and our US team is aware of this situation. We will respond to this situation by delivering our product without ceasing and by promoting development quickly.

Wakao [M]: Thank you. I understand very well. That is all.

Takechi [M]: Since there seems to be no one else with questions, I will conclude the question-and-answer session.

With that, we conclude the financial results briefing of Nippon Shinyaku for Q3 of FY2025. Thank you very much for joining us today.

[END]